IDENTIFYING THE ROLE OF PRE-HOSPITAL INTERCOSTAL CHEST DRAINS IN SOUTH AFRICA

by

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DECLARATION

I, **Enrico Dippenaar**, hereby declare that the work on which this dissertation/thesis is based is my original work (except where acknowledgements indicate otherwise) and that neither the whole work nor any part of it has been, is being, or is to be submitted for another degree in this or any other university.

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ABSTRACT

Background

Thoracic injury accounts for approximately one quarter of all traumatic deaths. Immediate life-threatening chest injuries include tension pneumothorax and haemothorax. These conditions can be treated in a definitive manner by appropriately trained and skilled practitioners within hospital emergency centres. Pre-hospital emergency care in South Africa only provides for therapeutic and temporary relief of a tension pneumothorax. Definitive care for both conditions, through an intercostal chest drain, remains limited to the hospital environment.

Aim/Objectives

To highlight issues, by identifying key components regarding the placement of intercostal chest drains in the pre-hospital South African environment.

Methods

This is a qualitative descriptive study. A modified Delphi technique was utilised throughout South Africa, followed by a Focus Group Interview within the Cape Town Metropole. Expansion of relevant issues was done from seven specific headings and their respective subheadings.

Results

22 experts (doctors and paramedics) within the emergency care field participated in the national Delphi study. 25 (20%) of the initial 123 statements obtained overall expert panel consensus, with a further 37 (30%) of the initial 123 statements revealing a majority agreement or disagreement pattern. A Focus Group Interview of 17 emergency medicine registrars generated a further 30 statements complimenting and validating the Delphi findings.

Conclusions

The role of pre-hospital intercostal chest drains in South Africa is clearly described, and is supported by expert insight. Further investigation is required for the potential inclusion of intercostal chest drains for pre-hospital emergency medical care in South Africa.

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DEFINITION OF KEY TERMS

Agreement:	Harmonisation of opinion in the act of agreeing.
Capabilities:	Skills and abilities set by the regulating authority.
Consensus:	Widespread agreement among group members.
Definitive Care:	Endpoint where required treatment can be administered with optimal care.
Disagreement:	Failure to agree.
Distribution Pattern:	Distinct pattern of agreement/disagreement which can be observed.
Gold Standard:	Method of treatment widely recognised as the best.
Haemothorax:	Collection of blood in the pleural space.
Needle Decompression:	Procedure whereby an intravenous needle with catheter is inserted into the chest for the purpose of expelling air from the pleural cavity.
Pneumothorax:	Collection of air in the pleural space.
Practitioner:	A person actively engaged in the medical field.
Procedure:	A medical course of action intended to achieve a result; with regard to this dissertation the 'procedure' relates to the placement of an Intercostal Chest Drain.
Seldinger Technique:	A medical procedure to obtain access to blood vessels and other hollow organs.
Trochar:	A medical instrument with a sharply pointed end used inside a hollow cannula.

ACRONYMS AND ABBREVIATIONS

ACLS	–	Advanced Cardiovascular Life Support
AEA/ANA	–	Ambulance Emergency Assistant
ALS	–	Advanced Life Support
ANT	–	Advanced Emergency Technician
ATLS	–	Advanced Trauma Life Support
AVPU	–	Alert, Voice, Pain, Unconscious
BAA	–	Basic Ambulance Assistant
BEMC	–	Bachelor Degree: Emergency Medical Care
BLS	–	Basic Life Support
BScEMC	–	Bachelor of Science: Emergency Medical Care
BTEMC	–	Bachelor of Technology: Emergency Medical Care
CCA	–	Critical Care Assistant
CPR	–	Cardio-Pulmonary Resuscitation
DipPEC	–	Diploma: Primary Emergency Care
EC	–	Emergency Centre
ECG	–	Electrocardiogram / Electrocardiograph
ECP	–	Emergency Care Practitioner
ECT	–	Emergency Care Technician
EMS	–	Emergency Medical Services
GCS	–	Glasgow Coma Scale
HEMS	–	Helicopter Emergency Medical Services
HPCSA	–	Health Professions Council of South Africa
ICD	–	Intercostal Chest Drain
ILS	–	Intermediate Life Support
IV	–	Intravenous
MMED	–	Masters in Medicine
MVA	–	Motor Vehicle Accident
NALS	–	Neonatal Advanced Life Support
NDEMC	–	National Diploma: Emergency Medical Care
PALS	–	Paediatric Advanced Life Support
PBEC	–	Professional Board Emergency Care

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CHAPTER 1

INTRODUCTION

1.1 Background

The last 20 years have seen great advancement in the field of emergency medicine and pre-hospital emergency medical care in South Africa [1, 2]. This growth has been in parallel with the evolution of the country as a whole. In the past, the South African health service as a developing system has mirrored healthcare systems from high income countries around the world, particularly the United States [3]. Locally, we have assimilated many of their practises to guide our health care advances [1, 3, 4].

The health system in South Africa has accepted the responsibility for the medical care and treatment of its people. This is further represented in the Constitution of South Africa (Act 108 of 1996), which states that all people of South Africa must have access to health care services and that no one may be refused emergency medical treatment [5].

In recent years, emergency care in South Africa both in-hospital and pre-hospital has grown to meet the needs of the more than 50 million, and growing, inhabitants of the country. This growth has led to an increase in education and profession credentialing to produce emergency medical staff that can deal effectively with the needs of the population.

With the high rate of poverty, unemployment and crime [6], South Africa currently has the highest proportional annual death rate in the world [3]. Emergency Medical Services (EMS) like hospital services are understaffed and poorly resourced to service the large area they cover [4, 6]. EMS provide emergency care within the community on a daily basis, where they are faced with the front line repercussions of violent crime and trauma [7]. These cases can be categorised in either blunt trauma or penetrating trauma [3].

Results of such blunt or penetrating chest trauma are varied, but primary concern is the development of a pneumothorax and/or haemothorax. These conditions affect the functioning of the respiratory system, and can lead to rapid deterioration of a patient's condition. They can occur in one lung or both, independently or simultaneously. A minor insult to the chest may result in a mild or small pneumothorax/haemothorax which may not be immediately life threatening. On the other hand, a larger more severe insult, or an untreated minor insult may lead to a tension-pneumothorax/haemothorax. These conditions, if not attended to immediately and appropriately, result in severe difficulty of breathing and can lead to sudden cardiac arrest and death.

A selected group of pre-hospital emergency care providers have been empowered to alleviate only one of these life threatening conditions (tension pneumothorax), by performing a needle thoracentesis [8]. This however only provides short term therapeutic relief by releasing a small amount of air from the pressurised lung cavity. The insertion of an Intercostal Chest Drain (ICD) is regarded as the definitive procedure for treating both pneumothorax and haemothorax [9]. This procedure is commonly performed by medical doctors within Emergency Centres (EC) throughout South Africa.

The development of pre-hospital emergency care to an advanced life support level has lifted the capability of emergency care, reaching those who need it most when they need it most. It would therefore seem a reasonable progression to bring such ICD treatment to the pre-hospital environment.

1.2 Motivation

Trauma is one of the commonest causes of death in middle to low income countries [10], with chest injuries responsible for 20 – 25% of these deaths [10 - 15]. This equates to a quarter of deaths as a result of chest injury [10]; with chest injuries occurring in approximately 60% of all poly-trauma cases [16]. Pneumothorax and/or haemothorax most frequently caused by chest trauma can cause or contribute substantially to death relating from such injury [13, 16].

EMS attends to a substantial number of emergency incidents within South Africa each year. The lack of resources [4, 6] to deal with an increasing number of emergency incidents, coupled with a constant population increase and demand on EMS, may lead to regular contact between pre-hospital emergency care practitioners and patients. During such emergency situations, patients may experience trauma related chest injury which may result in a pneumothorax, a haemothorax, or both.

Current emergency care capabilities only provides for the alleviation of a tension pneumothorax; through the insertion of a needle decompression, utilizing a 14 gauge intravenous (IV) catheterized needle and a one way valve [8]. Comparatively, such a sized catheterized needle is exceedingly smaller than a standard chest drain tube, providing only limited relief of air from the pleural cavity. This decompression procedure also does not allow for the relief of fluid from the pleural cavity. The accumulation of air or fluid within the pleural space can directly lead to respiratory and cardiovascular impairment [17, 18]. This may concurrently lead to the deterioration of a patient's condition in an emergency event, and may have fatal consequences. Insertion of an ICD is widely recommended as the 'gold standard' for the treatment of a traumatic pneumothorax and/or haemothorax [19].

The extended duration of time from onset of injury to definitive care (in-hospital), where such an ICD can be placed, may negatively affect patient outcome, morbidity and mortality [1]. It is therefore encouraged to investigate the placement of ICD's within the pre-hospital environment in South Africa; reducing the time to definitive care.

The number of patients each year that could benefit from pre-hospital ICD placement in South Africa is unknown. Currently this practise is reserved only for medical practitioners (doctors) and does not form part of the "capabilities of emergency care providers" [8] of any emergency care practitioner registered under the Professional Board for Emergency Care of the Health Professions Council of South Africa (HPCSA).

The formulation of a collected opinion from experts in the emergency care field in South Africa will enlighten the role of ICD's in the pre-hospital environment. This may be used as hypothesis and idea generation for potential future research, policy and clinical development in South Africa.

1.3 Aim

The aim of this study is to determine current opinion amongst emergency care experts, with regard to the placement of ICD's in the pre-hospital environment in South Africa.

1.4 Objectives

The first objective is to undertake a survey of emergency care experts to identify key components of relevance to the question of whether ICD's have a role in the pre-hospital environment in South Africa.

Based on the findings from the first study, the second objective is to further explore the issues raised in order to better understand these relevant issues related to ICD usage in the pre hospital environment.

The final objective is to establish recommendations aimed at hypothesis with idea generation for potential future research, policy and clinical development.

CHAPTER 2

LITERATURE REVIEW

2.1 South African Background

2.1.1 Emergency Medicine

Emergency medicine in South Africa is in its infancy compared to many developed countries throughout the world. Until 1994, whereby South Africa stepped into a new democracy, the country's health services were fragmented and access to efficient healthcare was reserved for certain ethnic groups only [4].

More recently the South African medical environment has been sharply divided on financial grounds [7]. This is evident in the establishment of the private health sector, whereby patients with the financial means or medical insurance have their choice of physician, hospital and all the benefits that "money can buy" [7]. Although the private healthcare system caters to less than 20% of the population in South Africa, it consumes around 70% of the finances and resources available [6].

It is evident in the latest National Census [20] that there is a large unemployment rate in South Africa. This equates to the majority of the population not being eligible for private healthcare, and the burden is placed on the under resourced public healthcare system [7, 6].

In South Africa, most government hospital EC's were modelled on the former United Kingdom (UK) system of 'Casualty Departments' [1]. These departments attend to large numbers of patients on a daily basis. Before the 21st Century, these units were staffed mainly by general medical practitioners with qualifications varying widely throughout the country [4].

The need to have appropriately qualified and credentialed practitioners working in EC's was clearly recognised. During the 1980's the first step to new development occurred in the form of a postgraduate Diploma in Primary Emergency Care (DipPEC) for medical practitioners. This program was initiated by the College of Medicine of South Africa for individuals pursuing their field of study. The attainment of this qualification required supervised activity practicing in casualty, intensive care units (ICU's) and anaesthesia for at least 6 months, followed by written examinations. This however does not qualify a practitioner the credential of speciality in the emergency medicine field. [4]

The advance in medical practitioner credentialing in primary emergency care is considered more marketable for practise in EC's. The private sector saw the potential of these practitioners working in their EC's and subsequently attracted most of these practitioners with increased employment benefits. [4]

The introduction of training programs such as Advanced Cardiovascular Life Support (ACLS), Advanced Trauma Life Support (ATLS), Paediatric Advanced Life Support (PALS), Neonatal Advanced Life Support (NALS), etc. brought about new interest and popularity in emergency medicine to practitioners not routinely exposed to acute resuscitation [1]. This helped lead to the development of an emergency medicine speciality in South Africa.

In 2003 the new speciality of emergency medicine was registered, and by 2013 there are around 100 specialists registered in this field [21]. The first few specialists in this field were awarded the emergency specialist title through fellowship programs. From there, a completed postgraduate Master in Medicine (MMed) program was established in 2004, with recognised emergency medicine examinations from the newly established College of Emergency Medicine of South Africa. This created a firm foundation for the new professional direction and for new registrar education. [6]

The responsibility of these specialists is theoretically sound, although implementation of their practise and their role in the South African health system are poorly established. Progress in emergency medicine received

government focus in preparations for the FIFA 2010 soccer World Cup, which boosted the field's growth significantly [6]. Definite reflection should now be carried out on a regular basis to establish future development of emergency medicine in South Africa.

2.1.2 Pre-hospital Emergency Medical Care

Before the abolishment of apartheid in 1994, and the emergence of a new Democratic Republic of South Africa, the country was internally divided into four distinct provinces. As far back as 1977, the country's Health Act (Health Act No. 63 of 1977) [22] made the provision of ambulance services the responsibility of the then four provincial administrations. These provinces inherited the basic ambulance services to serve communities within local government boundaries [1].

Early development of pre-hospital EMS saw the semi-detachment from traditional medical tiers in the creation of a 'new' frontier. This began with the rendering of ambulance services by the local fire departments. Only in the 1970's was the responsibility of the ambulance services changed by Section 16 of the Health Act, 1977 [22] to fall directly with the Provincial Health Department Administrations [2]. Remnants of the Fire and Ambulance Service was incorporated in the Fire Brigade Services Act (Act No. 99 of 1987) [23] which stipulates in its definition of 'service', paragraph (e) that: "subject to the provisions of the Health Act, 1977 (Act No. 63 of 1977), the rendering of an ambulance service as an integral part of the fire brigade service" [23].

Passionate leadership lead to the development and improvement of the ambulance service. Provincial ambulance training colleges were established, which began training ambulance personnel in basic, intermediate and later advanced medical care [2]. Development became more complex to a point where systems grew into self-sustaining departments. Progress did however vary between the existing provinces, and lead to numerous differences.

On the 10th of January 1992, various entities came together to establish a national Professional Board for Emergency Care Personnel, allowing registration with the South African Medical and Dental Council [2]. This signified professional status and created unity in South African pre-hospital emergency care. Nationwide regulation of training, performance, authority, registration and medical treatment protocol standards were implemented.

Post 1994 elections and the inauguration of new democratic leadership, the administration of the country changed dramatically. This change also rectified inequalities with regard to healthcare access. A new strategy was developed by the South African National Health Department which lead to the amendment of a new National Health Act in 2004 (Act No. 61 of 2003) [2, 24].

The formation of the Health Professions Council of South Africa (HPCSA), as amended to the Health Professions Act 1974 (Amendment Act 1 of 1998) [3], signified the era change. This national professions council is made up of several medical boards, which stand independently from each other [25]. This saw the Professional Board for Emergency Care (PBEC), as amended, reach full development. The appropriateness and effectiveness of this system is yet to be evaluated.

2.1.3 Pre-hospital Emergency Care Qualifications

Medical Doctors

The EMS, public or private, is responsible for providing primary emergency care and secondary critical care transport of patients throughout the community of South Africa. These services consist mainly of emergency care personnel, now called emergency care practitioners [25, 26], and medical doctors.

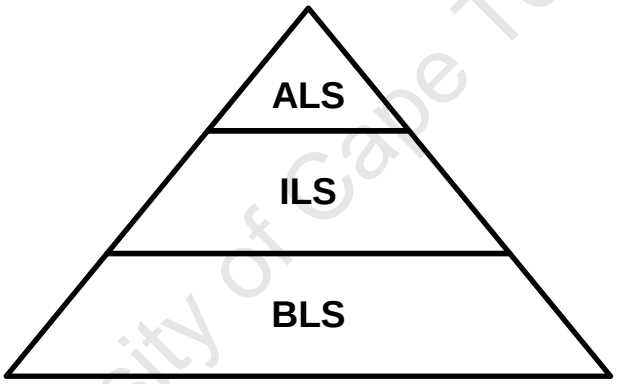
Medical doctors contribute only to a very small percentage of the pre-hospital treatment function of the EMS. It is very rare for general practitioners to interact in a pre-hospital capacity, and thus pre-hospital doctors usually have

special interest in emergency medicine. Most of these doctors have a DipPEC or are specialised as emergency physicians [1, 4, 6].

Short Courses in EMC

Limited resources and minimal pre-hospital physician availability has lead to the development of various levels of emergency care practitioner training, qualification and credentialing. The establishment of a three-tier system was adopted, beginning with the lowest basic life support (BLS), then intermediate life support (ILS), and highest advanced life support (ALS), as depicted in Table 1 [1, 2, 27 – 29]:

Table 1: *Three tier EMS qualification and credentialing system*



The pyramid display of Table 1 not only depicts the hierarchy of the credentials, but also illustrates the amount of practitioners qualified in each band. The latest available statistics from the HPCSA (as at 31 March 2013) has registered 51818 Basic Ambulance Assistants (BLS), 7539 Ambulance Emergency Assistants (ILS) and 1491 Paramedics (ALS) [30].

The initial responsibility for the education and training of emergency care workers were placed with local authorities and EMS institutions. Henceforth many ambulance training colleges were established [2], and these colleges offered 3 courses specific to each credential band: Basic Ambulance Assistant – (BLS), Ambulance Emergency Assistant – (ILS) and Paramedic – (ALS). It is also important to note that the Paramedic course was titled "Critical Care Assistant - CCA". Each of these certificate qualifications were

also registered with the HPCSA, with titles and abbreviations of BLS-BAA, ILS-ANA and ALS-ANT [1, 2, 26, 27]. Table 2 below represents the average course duration, although many variants in the durations were noted through the years as the courses grew and developed [1, 26, 27]:

Table 2: *Short course EMS durations*

COURSE:	BAA – BLS	AEA – ILS	(CCA) ANT - ALS
DURATION:	4 - 5 weeks	3 - 4 months	9 months

These qualifications and registrations also come with professional status, respective responsibility, and a scope of medical practise [26]. The scopes are determined by the level of training and education received by each tier and ranges from very basic to very advanced skills and medications [1, 2]. This has evolved extensively during the last 20 years as advancement in emergency research took place, with the ALS scope being the most increased and updated. Medical supervision over emergency care practitioners was in the form of an extension of a medical practitioner's licence, which had its advantages and disadvantages. Many factors influenced the change of supervision required to practise emergency care pre-hospital, and thus independent practise was awarded to the ILS and ALS bands; although the scope of practise and capabilities remain the framework under which to practise [21, 26, 31].

The short courses brought about intensive training in pre-hospital emergency care. Practitioners could be trained quicker compared to other higher education training in the medical field. The pass rate for ALS candidates remained low whereas BLS and ILS were vastly successful. This could be attributed to the intensiveness and difficulty of the course, and also perhaps explain why there are only so few ALS Paramedics registered. Through this, the short courses remained inferior with regard to higher education standards, as focus was only placed on one stream of training compared to multi-faceted holistic education [2]. The certificate attained through the short courses was never registered with the National Qualifications Framework

(NQF) as credit bearing, nor did it meet the requirements of the South African Qualifications Authority (SAQA); this means that academic articulation and progression would be very difficult [29].

Tertiary Institution Qualifications of EMC

In the mid to late 1980's a new program was developed and offered by the Witwatersrand and Natal Technicons. This 3-year National Diploma course was recognised by higher education standards and provided a more all around qualification and practitioner [2, 29]. Since the start of the National Diploma course, Technicons were integrated with each other and various Universities of Technology was formed, which expanded the Diploma course throughout the country to four universities in South Africa [26, 29]:

- University of Johannesburg
- Durban University of Technology
- Cape Peninsula University of Technology
- Central University of Technology

Diplomats were, and still are registered on the same register and level as Critical Care Assistants, on the Paramedic register – ANT; with similar scopes of practise, medication and capability guidelines. From the year 2000, Diplomats could further their studies to attain a Bachelor of Technology Degree in Emergency Medical Care. At this time there was no increase in scope of practise, and was seen as pure academic progression [27 – 29]. It was not until 2007 when a separate register was opened for degree qualified practitioners, called Emergency Care Practitioners and abbreviated ECP. In 2010 an increased scope of practise was added to this register to include mainly Rapid Sequence Intubation (RSI) and Thrombolysis [26, 29, 31].

Probably one of the most influential changes within the emergency medical care hierarchy is currently underway. This process was initiated by the Professional Board for Emergency Care (PBEC) in the early 2000's. The PBEC began evaluating the existence and future of short course training in combination with new directional changes of labour force education in South

African. The HPCSA together with its PBEC has expressed that they intend to stop short course training and new registrations to those categories. This has been met with fierce opposition by various private and public entities and thus far the status quo remains until the Minister of Health signs off on the discontinuation [29, 32].

Through this process, the PBEC has come forth with a new mid-level qualification called the Emergency Care Technician and abbreviated ECT. This 2-year National Certificate university qualification was created to replace and improve on the current short course training, and eventually phase out the current BLS and ILS registers. The new qualification also received ALS status, which is anecdotally a highly controversial topic throughout EMS communities [29]. Together with the creation of the ECP degree qualified practitioners in 2007, the ECT register came into being. [26, 27 – 29]

The ECT credential with its own scope of practise [26, 31] although considered ALS still falls short of the current full Paramedic scope of practise. The idea of the ECT is to create a mid-level worker whom could manage successfully most of the incidents and cases faced, and to reduce the amount of backup requests as is currently experienced. By increasing the number of ECT's out in the communities, resources can be consolidated and the gap between ILS and ALS could be decreased. This new development in EMS remains a topic of hot debate, and as time goes by the future and outcome of this movement will become clear [29].

Table 3 below depicts the various qualifications, their duration and the respective registers they fall under. These registrations represent the current Advanced Life Support band in the EMS structure, as enacted by the Minister of Health in the Government Gazette [33]:

Table 3: *Current ALS band EMS structure and course durations*

COURSE:	**DURATION:**	**REG:**
Emergency Care Technician	2 years full time	ECT
Critical Care Assistant	9 months full time	ANT
NDEMC	3 years full time	ANT
BTEMC	1 - 2 years part time post NDEMC	ECP
BEMC/BScEMC	4 years full time	ECP

The university based National Diploma (NDEMC) paramedics is on the same register as the short course based CCA paramedics, and with the move to create only a 2-tier EMS system, this qualification is also being phased out completely. It has been succeeded by the 4-year full-time Bachelors of Emergency Medical Care (BEMC), or Bachelors of Science in Emergency Medical Care (BScEMC), depending on the institution of study. Diplomats are also able to advance to this academic level by completing a Bachelors of Technology Degree in Emergency Medical Care (BTEMC). All of these degree qualifications enable registration with the HPCSA as a Registered Emergency Care Practitioner (ECP). [27, 29, 32, 33]

The Bachelor's Degree with its ECP registration is currently the highest clinical qualification for pre-hospital emergency care practitioners, having the largest scope of practise, capabilities and medicines list [31]. The qualification provides holistic education in all areas of medicine equal to any other professional medical qualification. It does not only focus on emergency medical care in the pre-hospital environment but also includes various rescue components. Overall this qualification meets the standards of the HPCSA and SAQA, and brings highly trained ALS to the pre-hospital South African environment.

2.2 Thoracic Injury

2.2.1 Background Incidence

Traumatic thoracic injuries are responsible for 25% of all trauma deaths [10 – 15]. Australian estimates suggested incidence of 12 persons per million of population per day are affected [14]. Whilst in the USA this figure is set higher at 19.4 per million of population, and in middle to low income countries like India it poses a staggering 34.5 per million of population per day [10]. This puts chest injuries as the 3rd most common cause of major trauma death, after head and limb injuries [10]. These injuries arise from penetrating trauma (gunshot or knife), and/or non-penetrating trauma (deceleration) – blunt trauma mechanisms such as motor vehicle accidents (MVA's) such as falls, crushes, blasts and burns [12].

Approximately 85% of all thoracic traumas can be treated without specialised surgical intervention [10, 11, 14, 34], which is only required in <10% of blunt and 15% – 30% of penetrating chest injuries [14, 15].

These injuries can rapidly deteriorate a patient's condition and can lead to traumatic cardiac arrest. Thoracic trauma is recognised as reversible cause of cardiac arrest and relies on rapid diagnosis and treatment [13]. Pre-hospital treatment following the recognition of these life-threatening chest injuries are often limited, leading to a delay in appropriate management [35]. Many chest injuries result in a pneumothorax and/or haemothorax, and may vary in degree of seriousness depending on the insult that caused them. Treatment of these life-threatening chest injuries is usually dealt with during the initial management phase at receiving hospitals [13, 14]. An aggressive pre-hospital approach to severe trauma patients with pleural drainage [15, 19, 36] by skilled medical crews has been shown to decreased mortality in some settings [36, 37].

2.2.2 Pathophysiology

A Pneumothorax and/or Haemothorax refer to a collection of air or blood respectively within the pleural cavity. This leads to a loss of negative

intra-pleural pressure and lung collapse [16, 38 – 40]. It is important to understand the various degrees by which these conditions may affect lung proficiency.

Simple Pneumo- and Haemothorax

These are the most common types and occur when air or blood enters the pleural space. As one of the lungs partially collapse the air or blood leak usually seals itself spontaneously. The intra-pleural pressure remains negative relative to the atmosphere, and there is no loss of function of any other intra-thoracic organs other than the affected lung [16, 38, 39]. In most instances these conditions are rectified by the body's homeostatic response, and do not require any surgical interventions.

Tension Pneumo- and Haemothorax

These are life-threatening conditions that occur if air or blood is able to enter the pleural space, despite complete collapse of the lung. This progressively reduces the negative pressure and increases the positive intra-pleural pressure. This causes deviation of the mediastinum away from the pneumothorax and/or haemothorax. It further compresses the contralateral lung and impairs venous return to the heart. Eventually death may result from a combination of absence of ventilation of either lung, and electromechanical dissociation of the heart. [11, 16, 38, 39] These conditions require rapid intervention through surgical means, to remove the air or blood mechanically [15, 41].

Open (sucking) Pneumothorax

This condition is also life-threatening as preferential movement of air in and out of the thorax, via a large defect or injury, results during respiration [11, 38, 39]. Rapid management is required to close the 'hole' in the chest and reduce further injury. Initial treatment can be achieved via various surgical or non-surgical means [10, 34].

2.2.3 Aetiology

Traumatic Pneumothorax

This condition may result from penetrating or blunt trauma to the chest. It may also be a result of a medical or surgical treatment in cases of central line insertion, percutaneous lung biopsy, pleural aspiration, and perforation during endoscopy; the afore-mentioned are called iatrogenic causes. The presence of multiple rib fractures with surgical emphysema strongly suggests an underlying pneumothorax and possible lung injury. Another cause include oesophageal trauma due to forceful vomit (Boerhaave's syndrome). [38, 39]

Traumatic Haemothorax

This condition is primarily caused by penetrating or blunt force trauma to the chest. It can also be iatrogenic as described previously. The extremely vascular thorax, with major arteries and veins running through it, could be severely affected by the associated trauma. Although the chest is protected by the rib cage, bleeding into the pleural space can occur with virtually any disruption of the tissues of the chest wall, pleura, or the intra-thoracic structures. [16]

2.2.4 Clinical Diagnosis

Diagnosis of pneumothorax and/or haemothorax should follow from an appropriate assessment of the chest and associated features. The Royal College of Surgeons of Edinburg describes this assessment by following a simple Look, Listen and Feel approach [35]. Their minimum standards of observation include:

- Respiratory rate
- Peripheral (radial) pulse rate
- Consciousness level (AVPU, GCS)
- Blood oxygen saturation
- Blood pressure
- Electrocardiogram (ECG) monitoring

The most common presenting symptoms of pneumothorax and/or haemothorax are pleuritic pain and dyspnoea. Reduced air entry, hyper- or hypo-resonance to percussion, and tracheal deviation may indicate a tension of either condition [38, 39]. The severity of symptoms does not always correlate directly to the size of the pneumothorax and/or haemothorax [39, 42]. However, the size usually reflects the severity of the inflicted injury [43]. The diagnosis of tension pneumothorax and/or haemothorax however is clinically dramatic and easily recognisable [11, 37]. Diminished breath sounds on the affected side, progressive dyspnea and tachypnea, jugular venous distension, tracheal shift, asymmetric chest expansion, and shock are commonly the clinical continuum of signs and symptoms with a tension pneumothorax and/or haemothorax [11, 44].

Table 4: *Royal College of Surgeons of Edinburgh diagnostic features*

Features	**Tension Pneumothorax**	**Open Pneumothorax**	**Massive Haemothorax**
Penetrating chest wound:	Possible	Yes, sucking	Possible
Reduced chest expansion on affected side:	Yes	Possible	Yes
Paradoxical movement:	No	No	No
Surgical emphysema:	Possible	Possible	No
Percussion note:	Very resonant	More resonant	Dull
Reduced air entry on affected side:	Yes	Yes	Yes
Neck veins:	May be distended	Normal	Flat
Trachea deviation:	Yes, but very late sign	No	Yes
Hypotension:	Yes, as late sign	No	Yes

2.3 Management

2.3.1 General Principles

There continues to be controversy about the best approach to the management of pneumothorax and/or haemothorax, and current guidelines vary in their recommendations [45 – 48]. Most agree that large pneumothoraxes and/or haemothorax are best managed with surgical procedures, especially in life threating tensioning states [45, 49]. The ultimate goal to drain the pleural cavity has remained constant [15], thus returning the negative intra-pleural pressure to normal.

The size of the pneumothorax and/or haemothorax, and its degree of respiratory compromise (symptoms, lung collapse) are determining factors in deciding what treatment options to follow. Small spontaneous pneumothorax and/or haemothorax do not always constitute surgical intervention, with observation being the first line treatment [38, 39, 47]. Open pneumothorax require rapid closure of the defect or 'hole' that causes air to enter the pleural cavity. Once this has been done, the patient can be evaluated and further treatment decided upon [11, 12, 35, 38, 39].

Tension pneumothorax and/or haemothorax are life-threatening emergencies that require immediate treatment [13, 38, 39, 41, 49, 50]. Rapid surgical drainage is required to relieve the increased pressure within the chest cavity [11, 13, 38, 39, 50]. Conventional treatment of tension pneumothorax is commonly managed by needle decompression followed by a chest tube insertion called an ICD [11, 12, 13, 38, 39, 41, 49, 50]. The procedure of simple thoracostomy has also been described as more effective than needle decompression, and a safer option to an ICD in uncontrolled and hostile environments [12, 48, 50].

2.3.2 Needle Decompression

As previously discussed, tension pneumothorax and/or haemothorax are life-threatening emergencies that require prompt drainage of the air and/or blood from the pleural cavity [13, 38, 39, 41, 49, 50]. Needle decompression is a

widely accepted ALS technique, and the standard of care for suspected tension pneumothorax in the pre-hospital environment [41, 44]. In South Africa, this procedure has also been included in pre-hospital emergency care capabilities [31]. Unfortunately, this procedure is only indicated for the relief of tension pneumothorax and cannot be utilised for the treatment of tension haemothorax [31]. Needle decompression is a relatively simple procedure, and most rapid method of achieving life-saving access to the pleural space; which may be performed without awaiting radiological imaging [12, 14, 41].

The needle decompression procedure consists of inserting a large-bore needle (e.g. IV cannula, 14G and 5cm long) into the second intercostal space in the mid-clavicular line of the affected hemi-thorax [11, 38, 39, 51]. The needle with its catheter is passed into the pleural space, whereby the metallic needle is removed and the catheter remains [31, 51]. A one-way valve (usually a small Heimlich valve) is attached to the external catheter, which allows air to be expelled from the pleural space to the atmosphere in one direction only. The catheter and one-way valve are then secured to the patient's chest and left in place to expel air and prevent further tensioning; until a definitive surgical drain can be inserted [11, 14, 38, 39].

There is little data documenting the incidence and efficacy of this treatment method in the pre-hospital environment [44]. Some studies have shown the possible unreliability of a needle decompression, and advocate the use thereof as a last resort procedure [14, 49]. Complications may lead to the failure of an effective needle decompression insertion [49]:

- The cannula may be of insufficient length to pass through the full thickness of the patient's chest wall.
- Air leaks from the lung can occur faster than it can escape through the cannula.
- Tissue/blood blockage of the cannula lumen can occur.
- High intra-thoracic pressure present in a tension pneumothorax results in compression of the chest wall tissues which may kink or obstruct the cannula.

There may also be possible positional or catheter length complications in the placement of a needle decompression [14]:

- Decompression of subcutaneous emphysema
- Intra-pulmonary placement in bulla or bronchial tree
- Needle which does not reach the pleural space
- Needle placement in a major vessel or the heart

2.3.3 Simple Thoracostomy

The procedure of simple thoracostomy has been controversial and with the availability of surgical chest drain placement, it is rarely used within the hospital environment. Field stabilisation of trauma patients and the rapid treatment of severe pneumothorax and/or haemothorax may favour this procedure above needle decompression pre-hospital. [14, 36, 50]

The procedure consists of a small incision (1 – 2cm) in the same area as a needle decompression (second intercostal space in the mid-clavicular line) [11, 38, 39, 51] or intercostal chest drain (usually the fifth intercostal space anterior to the mid-auxilliary line, in the 'triangle of safety') [34, 35, 38, 39, 52 – 57]. This follows blunt dissection and digital decompression through the pleura [14]. This creates a small opening for air and/or blood to drain from the pleural space.

This is in direct contrast to the recommendations for treating an open pneumothorax [11, 12, 31, 38, 39], which may lead to bleeding and cause an open pneumothorax by purposefully creating a 'hole' in the chest [35]. It is therefore advocated to perform endotracheal intubation concurrently with this procedure, to assist with lung expansion by providing ventilation support [36, 50]. Once the pneumothorax and/or haemothorax tension has subsided, the intentional wound 'hole' may be closed, or a one-way device inserted into it.

This procedure should only be performed in true life-threatening situations by trained practitioners, as open thoracostomy is a specialised technique [35].

Various Helicopter Emergency Medical Services (HEMS) in England and Italy have demonstrated the procedure to be safe, effective and improve survival of severe chest injury pre-hospital [47, 50]. It further has the advantage of being simpler and faster when compared to an ICD [47, 50].

2.3.4 Intercostal Chest Drain

History

Open drainage of empyema was performed as early as the fifth century BC. Censius described rib resection for empyema drainage in the fifteenth century AD [58]. Following the Franco-Prussian War of 1870/1 the German technique of pleural drainage was associated with a reduction in the development of empyema [14]. In 1873 Playfair performed closed drainage of the pleura in attempting to drain empyema; he resultantly found the solution to pneumothorax drainage by continuous underwater drainage [58]. The first documented description of a closed tube drainage system was by the more commonly known Hewett in 1876 [15, 52, 58]. In 1981 Thompson showed that bags with an integral non-return valve could also be used for chest drainage [59].

Underwater seal drainage as in its present form, using a simpler method of a single-bottle water-seal, was first described by Kenyon in 1916 and later by Lilienthal 1922, is considered the standard form of chest drainage [58, 59]. The First and Second World Wars together with the Vietnam War have also contributed greatly to the use of underwater seal drainage; it has become the standard of care for the management of chest trauma [14, 43, 52].

The three-bottle system consisting of collection, water-seal and manometer bottles was described by Howe in 1952 [59]. However, in 1968 a simpler unitised plastic system entered the market. The first mobile chest drain, a flutter valve called the Heimlich valve was introduced in 1968 [58, 59]. Improvements in chest drain insertion came from the Seldinger technique, and were originally described in 1953. It involves the use of an introducer (Thochar) needle to access the thoracic cavity with advancement of the guide

wire and the use of dilators [60]. Modern recommendations have shifted away from the Trochar usage due to its complication risk, and have been replaced with blunt dissection techniques [59, 61].

Equipment

Various sterile chest drain insertion packs are available for the placement of an ICD [57]. Traditional surgical tool kits are fairly standard and normally include disposables, instruments, sharps and antiseptic liquids [34, 57].

Drainage systems have improved from the initial underwater concepts of using a glass bottle and tubing that is placed below the water level [58]. Various derivatives from the standard system are being used in this modern era which includes plastic capturing bags with one way Heimlich flutter valves; this removes the use of the water system [58, 62, 63]. Portex® ambulatory chest drainage system chest bag [62, 64], Rocket® ambulatory chest drain [63], Asherman's chest seal and stoma bags with one-way valves [58] are examples of newly improved systems.

The 'Seldinger' technique and using a large Trochar needle to create a channel into the chest wall has been the standard for placement of ICD's [61, 65]. This has been modified and recommendations for blunt dissection are more favoured for safety reasons [48]. Argyle-type catheters are examples of this technique, which incorporates the guide-wire system [61]. The use of large bore chest tubes (27-28F) are the traditional sizes in use, yet studies have shown safety, tolerability and effectiveness to smaller bore (<14F) with a guide-wire system [61, 65 – 67].

In contrast, large or actively bleeding haemothorax may still require large bore tube insertion [16]. Simpler techniques for securing the drains to the chest wall have also been described [34, 35, 38, 39, 55 – 57, 68, 69].

Indications

When ICD's are necessary, the commonest underlying condition is a pneumothorax and/or haemothorax [43]. Not all pneumothorax and/or haemothorax require chest tube drainage [34, 56]. The size and symptoms of the underlying condition are usual indications for the insertion of a chest drain, which remains the 'gold standard' for chest drainage [19, 57].

Absolute emergency indications for ICD placement [35, 42, 55, 56, 60, 69]:

- Tension pneumothorax and/or haemothorax
- Massive and/or traumatic haemothorax
- A pneumothorax in a ventilated patient

Other indications for ICD placement is [35, 42, 55, 56, 60, 69]:

- Malignant pleural effusion
- Empyema and complicated parapneumonic pleural effusion
- Large secondary spontaneous pneumothorax in patients older than 50 years
- Persistent or recurrent pneumothorax and/or haemothorax after simple aspiration
- Iatrogenic (accidental puncture due to medical procedure) or postoperative (e.g. thoracotomy, oesophagectomy, cardiac surgery)

Procedure

The basic principle of a chest drain is to insert a tube into the pleural space to drain either air, blood or other fluid constituents. Specific procedure detail for ICD placement varies depending on local medical direction and authorities. The basic procedural steps for an ICD insertion includes indications, risk assessments, patient consent, equipment preparation, premedication, patient positioning, aseptic techniques, site of insertion identification, local analgesia, insertion of the tube, and tube securing [34, 35, 38, 39, 55 – 57, 69].

Complications

An ICD is often a life-saving procedure performed to treat severe chest injury [15]. The procedure is however not without risk and possible complication [70]. These complications may be exacerbated under urgent emergency conditions [70], or by inexperienced practitioners [53]. Numerous literatures highlight various complications and its rates regarding insertion of ICD's.

The 'Safe Triangle' also known as the 'Triangle of Safety', is widely described by numerous literatures [34, 38, 39, 52 – 54, 60, 69] as the most common and safest anatomic position for ICD insertion. The British Thoracic Society guidelines identifies the 'Safe Triangle' being within the anterior border of the latissimus dorsi, lateral border of the pectoralis major, line horizontal to the nipple and apex below the axilla; as viewed by Figure 1 below:

Figure 1*:* *Depiction of the 'Safe Triangle'*

Figure obtained through on-line open-source Google® images search: "intercostal chest drain" – June 2013 (liked to: www.almostadoctor.co.uk)

The complications of ICD's can be summarised as insertional, positional and infective as described below [14, 15, 34, 52, 53, 54, 60, 65, 70, 71]:

- Insertional – complications occur when the chest tube is inserted in the wrong anatomical position. The 'safe triangle' as described provides a safe margin to follow when inserting the drain tube, and avoids further unnecessary trauma to the chest.

- Positional – complications occur when the chest tube is misplaced within the chest cavity. Examples of this includes trauma to the inter-costal neurovascular bundle, extra-pleural placement, intra-fissural placement, intra-pulmonary placement, mediastinal impingement or penetration and trans-diaphragmatic placement.

- Infective – complications occur as a result of non-sterile chest tube placement or in septic environments, where the wound is exposed to bacterium. Infection can also occur if the wound is not managed appropriately post procedure.

It is important to realise that ICD's, although seen as a common procedure, still remains an invasive surgical procedure. Great care should be taken whilst performing the ICD procedure, and regular training and skill competency should be maintained. All the relevant literature reviewed in this regard [14, 15, 34, 52, 53, 54, 60, 65, 70, 71] support the notion that only trained and suitably experienced practitioners, in chest drainage, should perform this procedure in any setting.

CHAPTER 3

METHODOLOGY

3.1 Delphi Research Methodology

Linestone and Turoff in 1975 provided a basic definition of the Delphi Technique: “Delphi may be characterized as a method for structuring a group communication process so that the process is effective in allowing a group of individuals, as a whole, to deal with a complex problem” [72 – 75]. Thus, the method is a process of collecting and distilling expert opinion or judgement about a complex problem, by data collection and analysis techniques with combined feedback [75, 76].

The Delphi method is a well suited research instrument for seeking knowledge and understanding where there exists incomplete knowledge about a problem or phenomenon [75]. The use of a Delphi methodology has been widely favoured in various academic and non-academic fields. The technique has also been used in emergency medicine to establish performance indicators [77, 78], and there have also been other Delphi studies arising from South Africa in the past [78, 79]. The Delphi technique has been extensively described evaluated and analysed [72 – 93].

3.1.1 History

There is an overall consistency in literature of the Delphi technique which draws the origins of the method to the Rand Corporation in Santa Monica, California [81, 82, 90] which dates back to the 1950’s [72, 74, 75, 80 – 90]. The project was originally funded by the US Air Force [74, 84] to establish reliable consensus of opinion among experts [74, 75], and included long-range forecasting for strategic defence purposes [84]; this was the original “Project Delphi” [74]. The term “Delphi” came from the ancient Greek temple where the oracle could be found [86], from which prophecies were given [72]. An oracle refers: “someone of unquestioned wisdom and knowledge or of infallible authority” [72].

The initial structure of the technique consisted of intensive questionnaire rounds interspersed with controlled opinion feedback [84]. Inception of the original Delphi technique was by Dalkey and Helmer (1963) [75, 84, 88], and was further expanded upon by Linestone and Turnoff (1975) [72, 75, 80, 84, 86, 87]. Different variants and evolvement of the technique has also been extensively described [72, 74, 75, 80 – 90, 92]. It has developed to suite the needs of the applicable research and even became simplified with the use of technology, e.g. Web-based Delphi processes [93].

3.1.2 Elements and Characteristics

From all the evaluated literature on the Delphi research technique [72 – 93], a clear pattern emerges which describes the fundamental or basic principles of a Delphi study. The ultimate aim is to achieve consensus on relevant research issues and to gain knowledge about them. The table below represents the basic architecture of a Delphi study [72 – 93]:

Table 5: *Basic architecture of a Delphi study*

Subject selection:	It is first and foremost important to identify what needs to be addressed; what do we want/need to know.
Expert panel:	It should consist of participants with relevant experience and knowledge in the field of study.
Round 1:	This round consists of having the expert panel complete types of open-ended questions.
Round 2:	The data from round 1 is then relayed back to the expert panel for evaluation, which can be achieved though various means, possibly initiating consensus.
Round 3:	Further re-evaluation can be done from the round 2 results to create possible stronger consensus.
Further rounds:	Studies may include as many rounds as preferred in the attempt to establish consensus.

Data Analysis:	The data is analysed and depending on the subject of investigation, statistical representations are made.
Conclusions:	Conclusions are drawn from the data received which illustrates consensus variables and explores to what extent knowledge is gained about the 'problem'.

3.1.3 Strengths and Limitations

Every type of research has its strengths and its limitations [87] and it comes down to utilising the right 'tool' for the right 'job'. Within research instances the Delphi technique is beneficial when other methods are not adequate or appropriate for the data collection [72]. The primary strength of the Delphi technique is its ability to explore issues that require judgement [90]. It is a powerful technique when used to seek answers to appropriate questions [90].

The strength of the Delphi Technique is described by Steward (2001): "it has a capacity to capture those areas of collective knowledge that are held within professions but not often verbalised" [87]. Powel (2003) stated that: "The Delphi is exceptionally useful where the judgements of individuals are needed to address a lack of agreement or incomplete state of knowledge… the Delphi is particularly valued for its ability to structure and organise group communication" [87].

Delphi studies are difficult to perform well, and a great deal of attention should be given to the choice of participants and questionnaires [90]. Hsu & Sandford (2007) [88] presents shortcomings of the Delphi; that there may be a potential of low response rates, consumption of large blocks of time, potential of moulding opinions, and a potential of identifying general statements vs. specific topic related information.

Linstone and Turoff (1975) suggested there are five common reasons for Delphi to fail [72, 87]:

- Imposing monitor views and preconceptions of a problem upon the respondent group by over specifying the structure of the Delphi and not allowing for contribution of other perspectives related to the problem.
- Assuming that Delphi can be surrogate for all other human communications in a given situation.
- Poor techniques of summarizing and presenting the group response and ensuring common interpretations of the evaluation scales utilised in the exercise.
- Ignoring and not exploring disagreement so that discouraged dissenters drop out and an artificial consensus is generated.
- Understanding the demanding nature of a Delphi and the fact that the respondents should be recognised as consultants and properly compensated for their time if the Delphi is not an integral part of their job function.

3.2 Modified Delphi Study

3.2.1 Design

A qualitative descriptive paradigm [94] was chosen as best suited to establish an opinion base of emergency care experts in South Africa. The Delphi technique is the main method chosen to collect opinion based data.

It was important from the start to structure the knowledge this study hoped to gain. Through deliberation, it was established that six main themes of fundamental interest would guide and assemble the information gained. Under the six main headings, further delineation is given to sub-headings, which briefly tries to define the characteristics of the six main headings. A seventh and last heading was added to allow for unrestricted lateral and intuitive knowledge expansion.

The headings with its subsequent sub-headings are:

Pre-hospital intercostal chest drains (ICD's) in South Africa

- Need for procedure
    - Urban and Rural settings, Public and Private healthcare systems

- Safety of procedure
    - Risk (complications) vs. Benefit (improved patient outcomes)

- Diagnosis of major haemo-, pneumothorax
    - Indications, Contraindications, Methods of clinical diagnosis

- Effectiveness of procedure
    - Treatment of injury (haemo-, pneumothorax), Patient outcome measures

- Skill level required to perform procedure
    - Medical doctors, Emergency Care Practitioners, Paramedics

- Equipment
    - Required, Available to perform procedure

- Other
    - Any other issues regarding the placement of pre-hospital intercostal chest drains (ICD's) in South Africa

3.2.2 Setting

In an attempt to overcome limitations related to geographical spread of South Africa, the study was conducted nationally.

3.2.3 Population

It was important for the study to have a reasoned expert panel from the field of emergency medical care who could contribute their opinions in the formulation of a shared knowledge base, through experience. The Delphi study does not call for expert panels to be representative samples for

statistical purposes [73]. With the study setting being in South Africa, a relative homogenous population could be approached which required a smaller sample [75]. Thus, representation was better assessed on the qualities of the expert panel rather than its numbers [73].

It is however difficult to establish what constitutes a 'reasoned expert' in the field of pre-hospital emergency medical care. For the purpose of this study, emphasis was placed on the known emergency medical qualifications obtainable in South Africa, and the experience they have gained within the emergency care field. Through this, it is recognised that not all emergency care practitioners could be deemed as experts, and that further delineation was required. It was also important to have a population or expert panel whose members are registered with the Health Professions Council of South Africa (HPCSA).

The population for the study should be practitioners having at least an Advanced Life Support level capability. It is clear that two distinct groups or branches of emergency care exists, both of which bring specific insight and expertise to pre-hospital emergency medical care. Medical doctors are deemed to be higher qualified and experienced compared to pre-hospital ALS practitioners (Paramedics), yet their pre-hospital exposure is far less than that of paramedics. It is therefore important to involve both dynamics in the quest for knowledge about the subject.

It is assumed that not all medical doctors are experts in emergency care, and therefore it would be more appropriate to have doctors with the registered specialisation of emergency physician/specialist. The nature of an ICD procedure would furthermore lean suggestion to the involvement of trauma surgeons, specialists in traumatic invasive procedures. Emergency physicians and trauma surgeons undergo lengthy training to attain specialist recognition and registration with the HPCSA. This training allows for a vast amount of knowledge and experience to be ingrained in each practitioner, emphasising their 'reasoned expert' status.

In traditional paramedic qualification streams, both CCA's and NDEMC paramedics would undergo at least 3 years of training and experiential learning to become a registered paramedic with the HPCSA. The BTEMC program follows on an extra 2 years part time study, and with the recent introduction of the BEMC/BScEMC degrees, it would take a student 4 years to complete the qualification and registration as an ECP.

Taking into account the abovementioned qualifications and experience levels, this study defined its population to be:

- Emergency Physicians/Specialists
- Trauma Surgeons
- Registered Emergency Care Practitioners (ECP register), with more than five years' experience at an advanced life support level.
- Registered Paramedics (ANT register), with more than seven years' experience at an advanced life support level.

3.2.4 Sampling Strategy

Sampling Method

A non-probability, purposive, convenience sampling method was utilised for the small prospective population that would fit the inclusion criteria.

Invitations to participate in the voluntary modified Delphi study was sent out through the social network 'Facebook®' in several of its online communication forums. Official research participation invitations [Appendix 1] was sent to various Universities (Cape Peninsula University of Technology, Central University of Technology, Durban University of Technology, and the University of Johannesburg), government and private training colleges (KwaZulu Natal College of Emergency Care, Lebone College of Emergency Care, Provincial Government of the Western Cape College of Emergency Care, and Netcare911 School of Emergency and Critical Care), the Provincial Ambulance Services of the Western Cape, and individuals the researcher is acquainted with in the Cape Town Metropole.

The initial invitation brought interest to the topic, requested the spread of the invitation to other potential participants, and attempted to create enthusiasm for the upcoming study. The names and email addresses of the respondents were placed in a confidential and secure database for the purpose of the study. Once the modified Delphi study was ready for commencement, a complete package of invitations; the participant information leaflet, the participant consent form, and the link to the online questionnaire was sent to the individuals in study database. Further distribution was done through the University of Cape Town's Emergency Physician and Trauma Surgeon databases.

Inclusion Criteria

The aim of the sampling was to involve as many participants who fit the inclusion criteria as possible. Therefore all interested participants who qualified under the population criteria were allowed to participate in the study. Participants were also allowed to enter the modified Delphi study at any time during the first and second rounds.

Exclusion Criteria

Individuals who did not wish to participate in the study, or did not reply after two contact attempts for each round were excluded. Any individual who chose to discontinue or requested removal from the study were also excluded, and their data removed. Individuals who failed to comply with the set completion dates of the modified Delphi rounds were excluded from that round, yet communication regarding the progression of the study was still sent to them; unless otherwise requested. Reconsideration or re-entry into the study was allowed, except for round 3 of the modified Delphi.

3.2.5 Data Collection

The standard Delphi technique for research was adapted to suite the requirements of this research project. The nationally aimed study comprised of 3, on-line internet based, rounds using the 'SurveyMonkey®' database platform. The use of this platform was made available through the University

of Cape Town, and consists of user name and password protection. The researcher had access to the controlled platform and used it to create, distribute and collect the necessary data required for the study. The platform generated a specific link for each round, which was unique to each participants email IP address. This specific link was sent to each participant in the database during each round, and participants were able to complete, go back to, and change their input as they please before each rounds cut-off deadline.

Round 1

In round one, participants were asked to contribute statements, attributes or issues which they felt are important under the set headings, with subheadings provided. [Appendix 2] Free-text boxes were provided below each heading for statement input. These statements would be regarded as the expert's individual opinions relevant to the heading and overall study.

The first round commenced on the 3rd of August 2012 and was concluded on the 10th of September 2012. All statements provided by the participants were collected, organised and synthesised by the researcher to create specific opinion statements or themes from the raw data. It was important to generate final statements using objective wording that were relevant to the study and did not create ambiguity. Statements were ordered randomly under their initial headings not to create priority bias in the forthcoming rounds. [Appendix 3]

Round 2

In round 2, the statements from round one was re-functioned into the 'SurveyMonkey®' platform to create a Likert-scale [95] type questionnaire [Appendix 4]. The objective of this round was to try and establish consensus of opinion through a 9-point Likert-scale. This scale had the descriptions as described by table 6 below:

Table 6: *9-point Likert-scale*

1	2	3	4	5	6	7	8	9
Strongly Disagree		Disagree		Neither Agree nor Disagree	Agree		Strongly Agree	

From the Likert-scale, consensus is distinguished either positively or negatively regarding the specific statement that was reviewed by the participants. The second round commenced on the 1st of November 2012 and was concluded on the 23rd of November 2012.

Round 3

In round 3, the completed Likert-scale questionnaires from the internet platform was configured into individual 'Microsoft Excel®' spread sheets, unique to each participants input. A majority and/or trend were calculated for each statement from the Likert-scale input provided in round two. These individually specific documents were sent back to the participants for review. [Appendix 5] This gave the participants the opportunity to review their selections against the expert panel's majority and/or trend. At no point did the participants know who the other participants in the expert panel were, and thus they were allowed to change their input free of prejudice.

The third and final round commenced on the 3rd of December 2012 and was concluded on the 14th of December 2012. It was stated in the round commencement communication that only participants who wished to change their responses needed to reply, thus accepting no feedback as indication that the inputs from round two would remain unchanged.

3.2.6 Data Analysis

The nature of the research lends itself greatly to qualitative analysis, which is achieved throughout the study. Data collection through the modified Delphi introduces some quantitative attributes, useful as a verification and representation tool. In round one of the modified Delphi, identification of themes was the most important aspect of analysis. This was achieved through coding and categorising of the data collected. These themes generated from the 'opinions', for the purpose of this research, was organised and formulated according to the aim of the study. [73, 94] The first round Delphi data was presented in a narrative format for further use in the subsequent Delphi rounds, as well as for final interpretation in combination with the consensus findings.

The rounds 2 and 3 of the Delphi study gave rise to some simple ranking [82] and description [96]. Consensus or convergence of opinion is an underlying principle of any Delphi [87]. The decision of how consensus is measured remains with the researcher and the aim of the study [87]. The use of the 9-point Likert-Scale [95] makes it possible to create central tendency and dispersion scores [73] by expressing the numbers (points) that are most typical (mode) and those midpoint scores (median) in the distribution [94].

There are various means of determining the level of consensus or non-consensus. This can be established for the entire expert panel or delineated into specific groupings (i.e. Doctors vs. EMS). Firstly, attention was given to the agreement or disagreement level against any of the specific statements provided from round one. A combination of mode and median scores calculated with Excel® 'mode' and 'median' formulas [88, 94, 96] were utilised to determine the tendency of the groups opinion. The Second step was the determination of the strength of the consensus, thus the percentage of participants agreeing on the level of the statements. In this phase, the 'majority' score was refined to establish strong consensus on a specific statement; the stronger the consensus percentage is, the stronger the opinion relates to the study findings.

Through review during the study, and calculation of participant numbers, a consensus percentage of 60% [88] for strong agreement or disagreement was selected as appropriate for the design of the research. The set agreement or disagreement consensus served as the studies strongest evidence, tendencies not reaching the set consensus percentage was taken in consideration as strong evidence dependant on the 'median' and 'mode' scores. The final analysis of all the gathered data is of a narrative interpretative nature.

3.3 Focus Group Interview Research Methodology

Many authors have defined focus groups (or the Focus Group Interview):

- Morgan [97]: "The hallmark of a focus group is the explicit use of the group interaction to produce data and insights that would be less accessible without the interaction found in a group."
- Kotler [97]: "Groups of eight or twelve target consumers, usually (but not always) a relatively homogeneous group, brought together to discuss a specific set of issues under the guidance of a leader trained to stimulate and focus the discussion."
- Kreuger & Casey [98]: "carefully planned series of discussions designed to obtain perceptions on a defined area of interest in a permissive, nonthreatening environment."
- Powell [99]: "a group of individuals selected and assembled by researchers to discuss and comment on, from personal experience, the topic that is the subject of the research."

It is clear that there is no absolute definition for Focus Group Interviews, although ideas around the process remain similar. Small groups of people are approached and interviewed together in a semi-structured manner, under the guidance of a facilitator, whereby information in the form of perceptions, thoughts and impressions can be gathered about a specific topic [100 – 102].

3.3.1 History

As a research technique, focus group interviews or discussions have existed since the beginning of World War II [103]. The effectiveness of listening to radio programs designed to boost army morale was tested in group interviews [103, 104]. This method of qualitative data gathering was initially developed as an academic research method, but this has become more synonymous with market research since the 1950's [104]. Health and social sciences have also gained popularity for the use of these techniques in recent years [104]. Focus Group Interviews have also been adapted in certain cases to bridge the gap between quantitative and qualitative methodological approaches [105]. This form of data collection is a well known method which has received much attention in the research community and published literature.

3.3.2 Elements and Characteristics

There are various guidelines for conducting Focus Group Interviews: what it should consist of, how many and what type of people should be present, the questions asked, its duration, location, facilitator etc. [97 – 108]. It is important to establish what the goal is for Focus Group Interviews and to have a structured plan of conducting them efficiently. The below table describes some of the elements of focus group interviews, as summarised from the literature [97 – 108]:

Table 7: *Basic Elements of Focus Group Interviews*

Format:	Group session (usually a homogenous group of people). Many interviews can be held with different groups of people.
Participants:	Usually small groups not more than 12 specially selected participants. Participants are usually attracted voluntarily.
Length:	1 to 2 hours, or smaller sessions with breaks in between.
Environment:	Must be comfortable, usually circle seating.

Facilitator:	The facilitator has the important role to guide, manage and order the interviews objectively.
Questioning:	Questioning methods may differ depending on the need of the research. They can be structured, semi-structures, or open. In most cases, the questions are carefully predetermined and not more that 10 in total.
Data collection:	This can be achieved with audio recording devices, or simply having it directly transcribed. Participant conversation, tone and body language can all be interpreted.

3.3.3 Strengths and Limitations

As a qualitative tool that has re-emerged in social sciences, the question remains what makes Focus Group Interviews preferred above more traditional strategies, like participant observations, face-to-face interviewing and unobtrusive measures [103].

Functional advantages are that Focus Group Interviews are easy to undertake, they have a low cost, results can be obtained in a short period of time, the researcher can probe for clarification and solicit in greater detail, etc. [101, 102]. The most important reason for the use of this method, and its greatest advantage, is that investigation can be made and information elicited which allow researchers to establish 'Why' an issue is relevant or significant [99, 102].

Focus Group Interviews are very 'fragile' in some sense, as it is reliant on human action and interaction for its success. Highly skilled facilitators are required, groups are often difficult to assemble, individual responses are not independent of one another, and the results may not be appropriately representative [101]. Negative influences between group members may alter the process and the data collected. The instrument may cause for inappropriate generalisation of results and the results can be altered easily by the researcher to suite the desired research outcomes [102]. The 'human'

factor remains the core of this research method; it can produce significantly strong and valuable results, or in turn crumble the entire research strategy.

3.4 Focus Group Interview Study

3.4.1 Design

The same qualitative descriptive paradigm [94] and six main themes, with its sub-headings, was utilised for the Focus Group Interview. This was selected to round off and contextualise the Delphi findings.

3.4.2 Setting

It was recognised that through financial and time constraints that it would be near impossible to appropriately conduct various Focus Group Interviews throughout the whole country. A single Focus Group Interview was elected to round off the Delphi findings and therefore a focused approach was necessary confined to the Cape Town Metropole, within the Western Cape, South Africa. A high focus of emergency care experts in this region gave this selection appropriate reinforcement.

3.4.3 Population

Emergency medicine registrars from the Division of emergency medicine at the University of Cape Town were selected as the population for the Focus Group Interview. Although this population does not directly correlate with the 'reasoned expert' definition in the Delphi study, this population have sufficient gained knowledge through their studies, as a group, to formulate strong opinions as a collective.

3.4.4 Sampling Strategy

Sampling method

A purposeful and convenience sampling strategy was utilised for the Focus Group Interview [94].

Inclusion and Exclusion Criteria

The same fundamental principles were adopted as in the Delphi study, taking into account the new study population. The population consisted of qualified medical doctors enrolled as registrars in emergency medicine. Participation in the study remained voluntary, with respective consent attained.

3.4.5 Data Collection

Emergency medicine registrars were approached during one of their university contact lectures on the 27th of February 2013 at the IPM building on the Tygerberg Hospital grounds. The information collected during the interview was transcribed by the researcher during the session. [Appendix 6]

3.4.6 Analysis

The analysis of the Focus Group Interview is of a purely narrative coding and interpretation design [94]. The data gathered is contextualised with the findings of the Delphi study, to enlighten and possibly elaborate on its attributes.

3.5 Ethical Considerations

This study is focused on identifying the role of pre-hospital placement of ICD's in South Africa. This was done through the collection of expert opinions on the subject. It was therefore imperative to consider the risk and benefit to the individuals who participated in the study. This was a non-clinical study and referred only to the collection of participant experienced knowledge in emergency medical care, which relates to the study aim. The relevant University Faculty of Health Sciences Human Research Ethics Committee [Appendix 7] approval was attained before the start of data collection.

Relevant consent forms [Appendix 8] and research information [Appendix 9] was presented to the participants. These consent forms are kept confidential and only available to authorized persons on formal request.

This study comprised of two distinct methods, a modified Delphi study and a Focus Group Interview, which required coherent consideration. The anticipated gain in knowledge through both methods provided awareness and idea generation among the South African experts; relating to the placement of ICD's in the South African pre-hospital environment.

3.5.1 Risk to Participants

All participants are aware that they were the subject of the research study, and all of them had the option to refuse participation for any reason, at any time, without prejudice.

During the modified Delphi study, the participants personal contact details and individual replied statements was/is only available to the investigator. All data collected was/is stored on a password-protected personal computer. There was no anticipated downside to the participants other than the times spend completing the communicated documents.

At the Focus Group Interview, individuals may have felt vulnerable in participation. Although the participants were aware of each other, the studying atmosphere related to positive interaction. A protected environment for the expression of individual opinions was created. Individual authority was respected between the registrars on a high level.

3.5.2 Benefit to Participants

An enthusiastic group of individuals was eager to participate in this research study as they were regarded as subject experts in South African emergency medical care. Participants were able to provide their expert input, as part of an expert panel, on key issues that may affect South African pre-hospital emergency medicine directly in the future. A potential increase in personal and professional thoughts and understanding on the subject of pre-hospital emergency care may have been positively motivated.

CHAPTER 4

FINDINGS

4.1 Modified Delphi

The process of data collection for the Delphi study started on the 3rd of August 2012 with the first round, and concluded on the 14th of December 2012 with the third and final round. Round 1 specifically dealt with qualitative gathering of opinions under the formulated headings. Rounds 2 and 3 focused more creating consensus among the expert panel and refining that consensus through a Likert-scale rating system.

4.1.1 Round 1

The research design focused on six specific issues relating to the role of pre-hospital ICD's in South Africa. This was formulated to create six specific headings with sub-heading demeanours which described the nature of each heading. The specific headings were: 'Need for procedure', 'Safety of procedure', 'Diagnosis of major haemo,-pneumothorax', 'Effectiveness of procedure', 'Skill level required to perform procedure', and 'Equipment'. A seventh heading was added, 'Other', which intended to open discussion freely to the experts. The term 'Procedure' was defined throughout as referring to the placement of an ICD.

A free-text internet based questionnaire was sent to the respective participants. This process was open from 3rd August to 10th September 2012, and showed 27 individuals (Doctors = 11, EMS = 16) of which 16 participants (Doctors = 7, EMS = 9) completed the questionnaire, thus a 60% completion rate (n = 27).

Initial data screening after the round was done by transcribing the text collected and establishing concise statements. This process was done meticulously to steer true the opinions generated and to avoid subjective interpretation from the researcher. This process further followed various

drafting which included input from the study supervisor. The result of this development will now be described as the first round findings whereby 123 statements were formulated:

Table 8: ***Need for Procedure Statements*** *(19)*

1	There is a need for this procedure in the pre-hospital urban environment.
2	There is a need for this procedure in the pre-hospital rural environment.
3	The need for this procedure in the pre-hospital urban and rural environments is equal.
4	There is a need for this procedure in the pre-hospital private sector.
5	There is a need for this procedure in the pre-hospital public sector.
6	The need for this procedure in the pre-hospital private and public sectors is equal.
7	The need for this procedure increases in overloaded medical systems.
8	The patient's condition determines the need for this procedure pre-hospital.
9	The time from pre-hospital to hospital determines the pre-hospital need for this procedure.
10	The distance from pre-hospital to hospital determines the pre-hospital need for this procedure.
11	There is a need for this procedure where transport times to hospital exceed 30 minutes.
12	There is a need for this procedure where transport times to hospital exceed 60 minutes.
13	It would benefit patients if there are more providers of this procedure pre-hospital.
14	There is a need for this procedure pre-hospital for prolonged entrapped patients when indicated.
15	Patients will benefit greatly if this procedure is performed earlier.

16	There is a need for this procedure pre-hospital where indicated in cardio-pulmonary resuscitation.
17	There is a need for this procedure in aviation emergency medical care.
18	Where clinically indicated, this procedure limits morbidity and mortality.
19	Further studies are required to determine the need for this procedure pre-hospital.

Preliminary Valuation:

The need for the procedure was described by the participants in terms of, but not limited to: urban and rural environments, private and public sectors, patient condition, distance from hospital, time to hospital, prolonged entrapped patients, earlier performance of procedure, cardio-pulmonary resuscitation (CPR), aviation emergency medical care, morbidity and mortality, further studies required, etc.

Table 9: ***Safety of Procedure Statements*** *(26)*

20	The benefit of this procedure pre-hospital outweighs the risk.
21	The risk of infection outweighs the benefit of this procedure pre-hospital.
22	The risk of infection from this procedure pre-hospital can be suitably treated in-hospital.
23	Complications of this procedure pre-hospital can be suitably treated in-hospital.
24	Complications of this procedure pre-hospital can be limited by appropriate technique.
25	Practitioners should be able to manage possible complications appropriately pre-hospital.
26	This procedure has been seen performed successfully pre-hospital.
27	Patients seen treated with this procedure pre-hospital have benefitted greatly.

28	This procedure performed pre-hospital has shown minimal complications.
29	This procedure should be limited to controlled environments.
30	This procedure has shown improved patient clinical outcome in-hospital.
31	There is an increased risk using a Trochar device in performance of this procedure.
32	With appropriate training, this procedure should be safe when indicated pre-hospital.
33	There will be an increase in scene time if this procedure is performed pre-hospital.
34	An increase in scene time pre-hospital will negatively affect patient outcome.
35	Patients need to be transported rapidly to a hospital facility following this procedure.
36	This procedure can be done safely pre-hospital if practitioners are adequately trained.
37	This procedure can be done safely pre-hospital if practitioners are adequately equipped.
38	This procedure pre-hospital has the risk of introducing a haemothorax.
39	This procedure pre-hospital has the risk of introducing a pneumothorax.
40	Draining a large haemothorax pre-hospital may lead to uncontrollable bleeding.
41	This procedure pre-hospital would be purposeless where a patient requires a thoracotomy.
42	Where this procedure is clinically indicated it will potentially benefit peri-arrest patients.
43	This procedure performed pre-hospital will allow practitioners to successfully manage haemothorax.
44	This procedure performed pre-hospital will allow practitioners to successfully manage pneumothorax.

45	The benefit of this procedure pre-hospital outweighs the risk.

Preliminary Valuation:

The safety for the procedure was described by the participants in terms of, but not limited to: risk vs. benefit, infection, complications, pre-hospital vs. in-hospital, environment, devices, training, transport to hospital, clinical management, clinical outcome, etc.

Table 10: ***Diagnosis of Major Haemo-, Pneumothorax Statements*** *(25)*

46	Diagnosis of major haemothorax should only be clinical.
47	Diagnosis of major pneumothorax should only be clinical.
48	Practitioners should possess sound clinical judgement when diagnosing haemothorax.
49	Practitioners should possess sound clinical judgement when diagnosing pneumothorax.
50	Suitable pre-hospital clinical diagnosing methods should be utilised when diagnosing haemothorax.
51	Suitable pre-hospital clinical diagnosing methods should be utilised when diagnosing pneumothorax.
52	Suitable pre-hospital clinical diagnosing equipment should be utilised when diagnosing haemothorax.
53	Suitable pre-hospital clinical diagnosing equipment should be utilised when diagnosing pneumothorax.
54	A combination of clinical and special investigations should be utilised when diagnosing haemothorax.
55	A combination of clinical and special investigations should be utilised when diagnosing pneumothorax.
56	This procedure should only be done after X-ray diagnosis confirmation.
57	X-ray diagnosis and placement confirmation should be done after the procedure.

58	This procedure can be performed if diagnosing haemothorax is limited to clinical investigations.
59	This procedure can be performed if diagnosing pneumothorax is limited to clinical investigations.
60	If a needle thoracenthesis is indicated, so is this procedure.
61	This procedure should be limited to patients who are in immediate clinical danger.
62	Large haemothorax will not often be life threatening.
63	Large pneumothorax will not often be life threatening.
64	A massive pneumothorax has a low risk of tensioning if the patient is not positively pressure ventilated.
65	A tension pneumothorax must first be needle decompressed before attempting this procedure.
66	This procedure requires extensive patient monitoring.
67	Ultrasound is the method of choice for pre-hospital diagnosing of haemothorax.
68	Ultrasound is the method of choice for pre-hospital diagnosing of pneumothorax.
69	Evidence based guidelines and norms should apply when diagnosing haemothorax pre-hospital.
70	Evidence based guidelines and norms should apply when diagnosing pneumothorax pre-hospital.

Preliminary Valuation:

Diagnosis of major haemo-, pneumothorax was described by the participants in terms of, but not limited to: clinical diagnosis, clinical judgement, diagnosis equipment, special investigations, X-Ray, needle thoracenthesis, clinical danger, life threatening, patient monitoring, ultrasound, guidelines, etc.

Table 11: ***Effectiveness of Procedure Statements*** *(15)*

71	This procedure is the gold standard for treating haemothorax.
72	This procedure is the gold standard for treating pneumothorax.
73	Where indicated pre-hospital, this procedure will improve patient outcome.
74	This procedure performed pre-hospital will improve long-term patient outcome.
75	This procedure is effective if performed correctly pre-hospital.
76	Pre-hospital effectiveness of this procedure is difficult to measure.
77	Pre-hospital outcomes of this procedure should be measured against hospital outcomes.
78	There is a high morbidity from incorrect procedure placement pre-hospital.
79	Pre-hospital procedure efficacy can be assessed clinically.
80	This procedure is more effective than an informal needle decompression.
81	Long term efficacy of this procedure pre-hospital need to be through a monitoring perspective (in terms of infection and discharge from hospital).
82	Appropriate algorithms will guide practitioners to perform this procedure effectively pre-hospital.
83	Strict protocols need to be in place to ensure that patients' ultimately benefit from this procedure pre-hospital.
84	Consultation with suitable practitioners should be available prior to performing this procedure pre-hospital.
85	Consultation with suitable practitioners should be mandatory prior to performing this procedure pre-hospital.

Preliminary Valuation:

The effectiveness of the procedure was described by the participants in terms of, but not limited to: gold standard, patient outcome, correct procedure performance, outcome measures, morbidity, monitoring, algorithms, protocols, consultation, etc.

Table 12: ***Skill Level Required to Perform Procedure Statements*** *(11)*

86	Only medical doctors should be allowed to perform this procedure pre-hospital.
87	Medical doctors with ED or surgical experience are preferred to perform this procedure pre-hospital.
88	Specially trained professional nurses should be allowed to perform this procedure pre-hospital.
89	Emergency Care Practitioners (Degree qualified) with appropriate training should be allowed to perform this procedure pre-hospital.
90	All advanced life support practitioners with appropriate training should be allowed to perform this procedure pre-hospital.
91	All skill levelled practitioners can be trained to perform this procedure pre-hospital.
92	Mature and experienced practitioners are preferred to perform this procedure pre-hospital.
93	A high skill levelled practitioner is required to perform this procedure pre-hospital.
94	This procedure can be successfully performed by a single practitioner.
95	The performance of this procedure pre-hospital should form part of formal training.
96	This procedure can be selectively utilised pre-hospital by appropriately trained practitioners.

Preliminary Valuation:

The skill level required to perform the procedure was described by the participants in terms of, but not limited to: medical doctors, professional nurses, advanced life support practitioners, emergency care practitioners, experience, level of skill, formal training, etc.

Table 13: ***Equipment Statements*** *(12)*

97	All equipment used during this procedure pre-hospital should be sterile packaged.
98	Pre-packaged kits should be available to perform this procedure pre-hospital.
99	All kits used during this procedure pre-hospital should be sealed.
100	All kits used during this procedure pre-hospital should be standardised.
101	Appropriate equipment to perform this procedure pre-hospital is not currently available.
102	Similar equipment utilised in-hospital to perform this procedure should be utilised pre-hospital.
103	Similar equipment utilised on aeromedical services to perform this procedure should be utilised pre-hospital.
104	Sufficient cleansing solutions need to be utilised to reduce the risk of infection.
105	Appropriate monitoring equipment should be utilised to evaluate a patient's condition during performance of this procedure.
106	Alternative drainage devices are available to suit the pre-hospital environment.
107	Simplified procedure equipment can be utilised to suit the pre-hospital environment.
108	Simplified drainage devices can be utilised to suit the pre-hospital environment.

Preliminary Valuation:

The equipment required for the procedure was described by the participants in terms of, but not limited to: sterile packaging, pre-packaged kits, standardised kits, kits similar to other environments, cleansing solutions, monitoring equipment alternative drainage devices, procedure simplification, etc.

Table 14: ***Other Statements*** *(15)*

109	There is no need for this procedure pre-hospital in South Africa.
110	This procedure will lead to unnecessarily long pre-hospital scene time.
111	There is a big risk of misdiagnosing haemothorax pre-hospital.
112	There is a big risk of misdiagnosing pneumothorax pre-hospital.
113	A tension pneumothorax can be successfully managed with a needle decompression pre-hospital.
114	This procedure can be a module as part of the emergency care practitioner training.
115	Practitioners will have to maintain a high skill level to perform this procedure pre-hospital.
116	Integration with hospital trauma units is required to maintain practitioner competency in the performance of this procedure pre-hospital.
117	Regular training and skill maintenance of this procedure pre-hospital is required to maintain practitioner competency.
118	Training of this procedure pre-hospital should be conducted under the guidance of a suitable medical practitioner.
119	This procedure can be performed in transit.
120	Clinical governance and quality assurance need to be in place to manage the performance of this procedure pre-hospital.
121	A good record of information should be maintained regarding the performance of this procedure pre-hospital.

122	Uncontrolled conditions pre-hospital create hazardous complications to the performer of this procedure.
123	Clinical trails need to be carried out to establish the efficacy of this procedure pre-hospital.

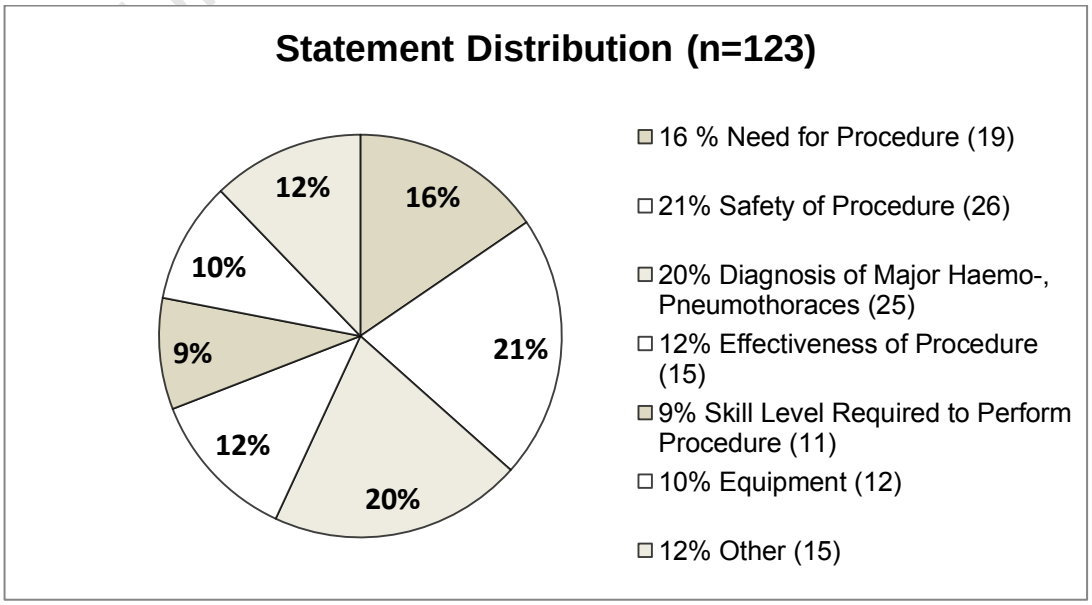
Preliminary Valuation:

Issues relating to the procedure (ICD) was described by the participants in terms of, but not limited to: pre-hospital scene time, misdiagnoses, needle decompression, modular training, high skill level, competency, skill maintenance, guidance, transit, clinical governance, information record, hazardous conditions and complications, clinical trails, etc.

Round 1 Synopsis

This round was successful in delivering expert opinion statements that could be utilised in rounds 2 and 3. Responses to the headings were fairly consistent, and the issues raised were fairly expected against the literature presented in chapter 2. From the outset it seemed that there were some differences of opinion, and a separation appeared between those individuals whom support the idea of pre-hospital intercostal drain insertion and those who do not.

Figure 2: *Distribution of the 123 Delphi Round 1 statements*



There are two headings that dominated response and evoked the most opinion statements, 'Safety of Procedure' and 'Diagnosis of Major Haemo-, Pneumothorax'. This may be an indicator that these headings are of most importance to the expert panel, and/or it may indicate that these headings are far more intricate and extensive than expected.

4.1.2 Round 2

The statements provided from round 1 were transposed and constructed into a new selection type Likert-scale questionnaire. This was sent out to the expert panel participants whom were able to rate their agreement or disagreement with the statements provided in an attempt to reach consensus.

Round 2 was initiated on the 1st of November 2012 and concluded on the 23rd of November 2012. 30 individuals (Doctors = 12, EMS = 18) replied of which 22 participants (Doctors = 8, EMS = 14) completed the questionnaire, a 73% completion rate.

Result

The tables below summarize the significant inputs of the expert panel relevant to the study. The most important data would be those statements that reached consensus, i.e. statements that receive complete consensus by either strong agreement or strong disagreement of the statement evaluated, of more than 60%. During the evaluation process, the statements that received 50% to 60% were also noted, as these statements could theoretically have the best chance of reaching consensus in the next round. An interesting phenomenon was observed as all consensuses were of an agreement nature towards the statements, with no consensus on disagreement of the statements.

The Tables below distinguish the results obtained by the Doctors and the EMS staff, with the final table combining the overall results to represent the complete expert panel; the statement numbers from Round 1 is utilised:

Table 15: *Statements from the **Doctors** group receiving ≥ 60% consensus on agreement of the statement provided:*

Need for Procedure	
8	The patient's condition determines the need for this procedure pre-hospital.
Safety of Procedure	
25	Practitioners should be able to manage possible complications appropriately pre-hospital.
31	There is an increased risk using a Trochar device in performance of this procedure.
Diagnosis of Major Haemo-, Pneumothorax	
57	X-ray diagnosis and placement confirmation should be done after the procedure.
69	Evidence based guidelines and norms should apply when diagnosing haemothorax pre-hospital.
70	Evidence based guidelines and norms should apply when diagnosing pneumothorax pre-hospital.
Effectiveness of Procedure	
71	This procedure is the gold standard for treating haemothorax.
78	There is a high morbidity from incorrect procedure placement pre-hospital.
85	Consultation with suitable practitioners should be mandatory prior to performing this procedure pre-hospital.
Skill Level Required to Perform Procedure	
No statements under this heading reached consensus.	
Equipment	
97	All equipment used during this procedure pre-hospital should be sterile packaged.
98	Pre-packaged kits should be available to perform this procedure pre-hospital.

99	All kits used during this procedure pre-hospital should be sealed.
100	All kits used during this procedure pre-hospital should be standardised.
103	Similar equipment utilised on aeromedical services to perform this procedure should be utilised pre-hospital.
104	Sufficient cleansing solutions need to be utilised to reduce the risk of infection.
105	Appropriate monitoring equipment should be utilised to evaluate a patient's condition during performance of this procedure.
Other	
116	Integration with hospital trauma units is required to maintain practitioner competency in the performance of this procedure pre-hospital.
117	Regular training and skill maintenance of this procedure pre-hospital is required to maintain practitioner competency.
118	Training of this procedure pre-hospital should be conducted under the guidance of a suitable medical practitioner.
120	Clinical governance and quality assurance need to be in place to manage the performance of this procedure pre-hospital.
121	A good record of information should be maintained regarding the performance of this procedure pre-hospital.

Table 16: *Statements from the **EMS** group receiving ≥ 60% consensus on agreement of the statement provided:*

Need for Procedure	
12	There is a need for this procedure where transport times to hospital exceed 60 minutes.
17	There is a need for this procedure in aviation emergency medical care.
Safety of Procedure	
No statements under this heading reached consensus.	

Diagnosis of Major Haemo-, Pneumothorax	
48	Practitioners should possess sound clinical judgement when diagnosing haemothorax.
49	Practitioners should possess sound clinical judgement when diagnosing pneumothorax.
Effectiveness of Procedure	
No statements under this heading reached consensus.	
Skill Level Required to Perform Procedure	
No statements under this heading reached consensus.	
Equipment	
97	All equipment used during this procedure pre-hospital should be sterile packaged.
98	Pre-packaged kits should be available to perform this procedure pre-hospital.
99	All kits used during this procedure pre-hospital should be sealed.
100	All kits used during this procedure pre-hospital should be standardised.
104	Sufficient cleansing solutions need to be utilised to reduce the risk of infection.
105	Appropriate monitoring equipment should be utilised to evaluate a patient's condition during performance of this procedure.
Other	
115	Practitioners will have to maintain a high skill level to perform this procedure pre-hospital.
120	Clinical governance and quality assurance need to be in place to manage the performance of this procedure pre-hospital.
121	A good record of information should be maintained regarding the performance of this procedure pre-hospital.

Table 17: *Statements from the **Doctors** and **EMS** groups combined receiving ≥ 60% consensus on agreement of the statement provided:*

Need for Procedure	
8	The patient's condition determines the need for this procedure pre-hospital.
17	There is a need for this procedure in aviation emergency medical care.
Safety of Procedure	
25	Practitioners should be able to manage possible complications appropriately pre-hospital.
31	There is an increased risk using a Trochar device in performance of this procedure.
Diagnosis of Major Haemo-, Pneumothorax	
48	Practitioners should possess sound clinical judgement when diagnosing haemothorax.
49	Practitioners should possess sound clinical judgement when diagnosing pneumothorax.
57	X-ray diagnosis and placement confirmation should be done after the procedure.
69	Evidence based guidelines and norms should apply when diagnosing haemothorax pre-hospital.
70	Evidence based guidelines and norms should apply when diagnosing pneumothorax pre-hospital.
Effectiveness of Procedure	
No statements under this heading reached consensus.	
Skill Level Required to Perform Procedure	
No statements under this heading reached consensus.	
Equipment	
97	All equipment used during this procedure pre-hospital should be sterile packaged.

98	Pre-packaged kits should be available to perform this procedure pre-hospital.
99	All kits used during this procedure pre-hospital should be sealed.
100	All kits used during this procedure pre-hospital should be standardised.
103	Similar equipment utilised on aeromedical services to perform this procedure should be utilised pre-hospital.
104	Sufficient cleansing solutions need to be utilised to reduce the risk of infection.
105	Appropriate monitoring equipment should be utilised to evaluate a patient's condition during performance of this procedure.
Other	
115	Practitioners will have to maintain a high skill level to perform this procedure pre-hospital.
117	Regular training and skill maintenance of this procedure pre-hospital is required to maintain practitioner competency.
118	Training of this procedure pre-hospital should be conducted under the guidance of a suitable medical practitioner.
120	Clinical governance and quality assurance need to be in place to manage the performance of this procedure pre-hospital.
121	A good record of information should be maintained regarding the performance of this procedure pre-hospital.

Round 2 Synopsis

This round was conducted successfully and produced respectable results for the study purpose. It is apparent at a quick glance that only a few statements reached complete consensus. There also seems to be less overall panel consensus on the statements compared to when the Doctors and EMS groups are separated. There where 13 statements under Doctors (16%, n=123), 21 under EMS (26%, n=123), and 21 overall which reached consensus (26%, n=123).

4.1.3 Round 3

The Likert-scale rating of the statements which were presented by the participants in Round 2 was collated to provide median and mode scores respectively. The trend of the expert panel was then calculated on the median and mode scores and presented back to the expert panel for re-evaluation. This involved sending the participants 'Excel®' sheets which presented them with their own Round 2 input and the expert panel trend. It was then up the participants to decide if they would like to change their input in light of the panel's trend opinion.

Round 3 was initiated on the 3rd of December 2012 and concluded on the 14th of December 2012. Of the 22 participants to whom the round was sent (Doctors = 8, EMS = 14), 12 (55%, n=22) replied to the review of which 9 (41%, n=22 and 75%, n=12) made changes to their original inputs.

Result

The structure of analysis and construction of the result follows the same format as that of Round 2. This point of the research indicated completion of the Delphi data collection. It should be noted that during the re-evaluations of Round 3, certain statements could have lost consensus on the specific Likert-scale scores. A positive agreement or disagreement distribution pattern was recognised in relation to the Likert-scale results. Thus, the overall trend of the expert panel can be either leading to agreement ('Agree' + 'Strongly Agree'; 6 – 9 on the Likert-scale) or disagreement ('Disagree' + 'Strongly Disagree'; 1 – 4 on the Likert-scale) of the statements provided.

The research is of a qualitative nature, and as such an overall distribution pattern is just as important as reaching consensus on the statements. For this purpose, a higher percentage including and above 75% was selected to reflect the dispersion of the Likert-scale results towards either 'strongly agree' or 'strongly disagree'. This distribution pattern can also be used in the discussion alongside the statements that reached consensus to further strengthen the consensus findings.

Table 18: *Statements from the **Doctors** group receiving ≥ 60% consensus on agreement of the statement provided:*

Need for Procedure	
8	The patient's condition determines the need for this procedure pre-hospital.
17	There is a need for this procedure in aviation emergency medical care.
Safety of Procedure	
25	Practitioners should be able to manage possible complications appropriately pre-hospital.
31	There is an increased risk using a Trochar device in performance of this procedure.
34	An increase in scene time pre-hospital will negatively affect patient outcome.
Diagnosis of Major Haemo-, Pneumothorax	
57	X-ray diagnosis and placement confirmation should be done after the procedure.
69	Evidence based guidelines and norms should apply when diagnosing haemothorax pre-hospital.
70	Evidence based guidelines and norms should apply when diagnosing pneumothorax pre-hospital.
Effectiveness of Procedure	
71	This procedure is the gold standard for treating haemothorax.
78	There is a high morbidity from incorrect procedure placement pre-hospital.
81	Long term efficacy of this procedure pre-hospital need to be through a monitoring perspective (in terms of infection and discharge from hospital).
84	Consultation with suitable practitioners should be available prior to performing this procedure pre-hospital.
85	Consultation with suitable practitioners should be mandatory prior to performing this procedure pre-hospital.

Skill Level Required to Perform Procedure	
Still no statements under this heading reached consensus.	
Equipment	
97	All equipment used during this procedure pre-hospital should be sterile packaged.
98	Pre-packaged kits should be available to perform this procedure pre-hospital.
99	All kits used during this procedure pre-hospital should be sealed.
100	All kits used during this procedure pre-hospital should be standardised.
103	Similar equipment utilised on aeromedical services to perform this procedure should be utilised pre-hospital.
104	Sufficient cleansing solutions need to be utilised to reduce the risk of infection.
105	Appropriate monitoring equipment should be utilised to evaluate a patient's condition during performance of this procedure.
Other	
115	Practitioners will have to maintain a high skill level to perform this procedure pre-hospital.
116	Integration with hospital trauma units is required to maintain practitioner competency in the performance of this procedure pre-hospital.
117	Regular training and skill maintenance of this procedure pre-hospital is required to maintain practitioner competency.
118	Training of this procedure pre-hospital should be conducted under the guidance of a suitable medical practitioner.
120	Clinical governance and quality assurance need to be in place to manage the performance of this procedure pre-hospital.
121	A good record of information should be maintained regarding the performance of this procedure pre-hospital.
122	Uncontrolled conditions pre-hospital create hazardous complications to the performer of this procedure.

Table 19: *Statements from the **EMS** group receiving ≥ 60% consensus on agreement of the statement provided:*

Need for Procedure	
8	The patient's condition determines the need for this procedure pre-hospital.
12	There is a need for this procedure where transport times to hospital exceed 60 minutes.
17	There is a need for this procedure in aviation emergency medical care.
Safety of Procedure	
25	Practitioners should be able to manage possible complications appropriately pre-hospital.
30	This procedure has shown improved patient clinical outcome in-hospital.
31	There is an increased risk using a Trochar device in performance of this procedure.
Diagnosis of Major Haemo-, Pneumothorax	
48	Practitioners should possess sound clinical judgement when diagnosing haemothorax.
49	Practitioners should possess sound clinical judgement when diagnosing pneumothorax.
Effectiveness of Procedure	
84	Consultation with suitable practitioners should be available prior to performing this procedure pre-hospital.
Skill Level Required to Perform Procedure	
No statements under this heading reached consensus.	
Equipment	
97	All equipment used during this procedure pre-hospital should be sterile packaged.
98	Pre-packaged kits should be available to perform this procedure pre-hospital.

99	All kits used during this procedure pre-hospital should be sealed.
100	All kits used during this procedure pre-hospital should be standardised.
104	Sufficient cleansing solutions need to be utilised to reduce the risk of infection.
105	Appropriate monitoring equipment should be utilised to evaluate a patient's condition during performance of this procedure.
Other	
115	Practitioners will have to maintain a high skill level to perform this procedure pre-hospital.
117	Regular training and skill maintenance of this procedure pre-hospital is required to maintain practitioner competency.
118	Training of this procedure pre-hospital should be conducted under the guidance of a suitable medical practitioner.
120	Clinical governance and quality assurance need to be in place to manage the performance of this procedure pre-hospital.
121	A good record of information should be maintained regarding the performance of this procedure pre-hospital.

Table 20: *Statements from the **Doctors** and **EMS** groups combined receiving ≥ 60% consensus on agreement of the statement provided:*

Need for Procedure	
8	The patient's condition determines the need for this procedure pre-hospital.
12	There is a need for this procedure where transport times to hospital exceed 60 minutes.
17	There is a need for this procedure in aviation emergency medical care.
Safety of Procedure	
25	Practitioners should be able to manage possible complications appropriately pre-hospital.

31	There is an increased risk using a Trochar device in performance of this procedure.
Diagnosis of Major Haemo-, Pneumothorax	
48	Practitioners should possess sound clinical judgement when diagnosing haemothorax.
49	Practitioners should possess sound clinical judgement when diagnosing pneumothorax.
57	X-ray diagnosis and placement confirmation should be done after the procedure.
69	Evidence based guidelines and norms should apply when diagnosing haemothorax pre-hospital.
70	Evidence based guidelines and norms should apply when diagnosing pneumothorax pre-hospital.
Effectiveness of Procedure	
81	Long term efficacy of this procedure pre-hospital need to be through a monitoring perspective (in terms of infection and discharge from hospital).
84	Consultation with suitable practitioners should be available prior to performing this procedure pre-hospital.
Skill Level Required to Perform Procedure	
No statements under this heading reached consensus.	
Equipment	
97	All equipment used during this procedure pre-hospital should be sterile packaged.
98	Pre-packaged kits should be available to perform this procedure pre-hospital.
99	All kits used during this procedure pre-hospital should be sealed.
100	All kits used during this procedure pre-hospital should be standardised.
103	Similar equipment utilised on aeromedical services to perform this procedure should be utilised pre-hospital.

104	Sufficient cleansing solutions need to be utilised to reduce the risk of infection.
105	Appropriate monitoring equipment should be utilised to evaluate a patient's condition during performance of this procedure.
Other	
115	Practitioners will have to maintain a high skill level to perform this procedure pre-hospital.
116	Integration with hospital trauma units is required to maintain practitioner competency in the performance of this procedure pre-hospital.
117	Regular training and skill maintenance of this procedure pre-hospital is required to maintain practitioner competency.
118	Training of this procedure pre-hospital should be conducted under the guidance of a suitable medical practitioner.
120	Clinical governance and quality assurance need to be in place to manage the performance of this procedure pre-hospital.
121	A good record of information should be maintained regarding the performance of this procedure pre-hospital.

Table 21: *Statements from the **Doctors** and **EMS** groups combined receiving ≥ 75% result dispersion towards agreement of the statement provided:*

Need for Procedure	
9	The time from pre-hospital to hospital determines the pre-hospital need for this procedure.
18	Where clinically indicated, this procedure limits morbidity and mortality.
19	Further studies are required to determine the need for this procedure pre-hospital.
Safety of Procedure	
24	Complications of this procedure pre-hospital can be limited by appropriate technique.

33	There will be an increase in scene time if this procedure is performed pre-hospital.
34	An increase in scene time pre-hospital will negatively affect patient outcome.
38	This procedure pre-hospital has the risk of introducing a haemothorax.
39	This procedure pre-hospital has the risk of introducing a pneumothorax.
40	Draining a large haemothorax pre-hospital may lead to uncontrollable bleeding.
44	This procedure performed pre-hospital will allow practitioners to successfully manage pneumothorax.
Diagnosis of Major Haemo-, Pneumothorax	
50	Suitable pre-hospital clinical diagnosing methods should be utilised when diagnosing haemothorax.
51	Suitable pre-hospital clinical diagnosing methods should be utilised when diagnosing pneumothorax.
52	Suitable pre-hospital clinical diagnosing equipment should be utilised when diagnosing haemothorax.
53	Suitable pre-hospital clinical diagnosing equipment should be utilised when diagnosing pneumothorax.
54	A combination of clinical and special investigations should be utilised when diagnosing haemothorax.
55	A combination of clinical and special investigations should be utilised when diagnosing pneumothorax.
Effectiveness of Procedure	
71	This procedure is the gold standard for treating haemothorax.
72	This procedure is the gold standard for treating pneumothorax.
75	This procedure is effective if performed correctly pre-hospital.
77	Pre-hospital outcomes of this procedure should be measured against hospital outcomes.

80	This procedure is more effective than an informal needle decompression.
82	Appropriate algorithms will guide practitioners to perform this procedure effectively pre-hospital.
83	Strict protocols need to be in place to ensure that patients' ultimately benefit from this procedure pre-hospital.
Skill Level Required to Perform Procedure	
89	Emergency Care Practitioners (Degree qualified) with appropriate training should be allowed to perform this procedure pre-hospital.
93	A high skill levelled practitioner is required to perform this procedure pre-hospital.
95	The performance of this procedure pre-hospital should form part of formal training.
96	This procedure can be selectively utilised pre-hospital by appropriately trained practitioners.
Equipment	
102	Similar equipment utilised in-hospital to perform this procedure should be utilised pre-hospital.
107	Simplified procedure equipment can be utilised to suit the pre-hospital environment.
108	Simplified drainage devices can be utilised to suit the pre-hospital environment.
Other	
122	Uncontrolled conditions pre-hospital create hazardous complications to the performer of this procedure.
123	Clinical trails need to be carried out to establish the efficacy of this procedure pre-hospital.

Table 22: *Statements from the **Doctors** and **EMS** groups combined receiving ≥ 75% % result dispersion towards disagreement of the statement provided:*

Need for Procedure	
3	The need for this procedure in the pre-hospital urban and rural environments is equal.
Diagnosis of Major Haemo-, Pneumothorax	
56	This procedure should only be done after X-ray diagnosis confirmation.
62	Large haemothorax will not often be life threatening.
63	Large pneumothorax will not often be life threatening.
Skill Level Required to Perform Procedure	
86	Only medical doctors should be allowed to perform this procedure pre-hospital.

Round 3 Synopsis

This 3rd and final round concluded the Delphi section of the research successfully. Initial summary of the data evolution process reveals that 27 (22%, n=123) statements received complete consensus in the Doctors group, 20 (16%, n=123) in the EMS group, and 25 (20%, n=123) for the overall expert panel. Round 3 saw an increase in consensus for all three groupings from the initial ratings of Round 2, whilst general distribution remained the same. The greater inclination towards one side or the other in the distribution pattern shows a level of secondary or implied consensus, with 37 (30%) of the statements receiving either dispersion towards agreement (32) or towards disagreement (5) on the statements.

4.2 Focus Group Interview

The second part of the research included a Focus Group Interview with Emergency Physician Registrars in the Cape Town Metropole. 17 Registrars participated in the interview on the 27th of February 2013.

A description and outline of the study was given to the participants with focus on the purpose of the Focus Group Interview.

The group was presented with the same six specific headings and the one non-specific heading, as was utilised in the Delphi study. Preliminary findings from the Delphi were concurrently presented to the participants as an added frame of reference.

Notes on the discussion themes under each heading were transcribed during the interview to capture only the fundamental ideas and opinions of the group as a whole. The rough transcription was then re-formulated into specific sentence and phrase statements.

4.2.1 Need for Procedure

- The group found it unclear/uncertain of what particular type of need there is for this procedure in the pre-hospital environment, but does agree that there is some sort of anecdotal need which is prevalent in the increased incidents of chest trauma in SA.
- The group expressed their concerned of Urban vs. Rural need, though acknowledges a national protocol driven framework.
- Short transport times to hospital may negate the need for ICD placement pre-hospital.
- The group does support possible insertion during CPR, if indications are present.
- Should have the procedure available pre-hospital if the need arises.
- Further specific study is needed to determine exact need.
- Pre-hospital need may be greater for unstable life threatening cases; this needs analysis.

4.2.2 Safety of Procedure

- The group unanimously agree that the procedure can be done safely in the pre-hospital environment, though sterility is a concern.
- Risk vs. Benefit analysis will have to be determined on an individual case and circumstance basis.
- Treatment of ICD placement complications is a concern pre-hospital, though ALS practitioners should be able to manage such complications till arrival at hospital.
- The procedure should be safe if effective training, equipment and SOP's (Standard Operating Procedures) are in place.

4.2.3 Diagnosis of Major Haemo-, Pnemothorax

- ALS practitioners should be able to diagnose such conditions accurately.
- Clinical diagnosis alone can be done successfully by ALS practitioners.
- Diagnosis of minor Haemo-, Pneumothorax may not require ICD placement pre-hospital.
- X-Ray and portable Ultrasound need not be necessary in life threatening cases, though placement has to be confirmed in-hospital.
- Clear indications should be set up and met prior ICD insertion pre-hospital.

4.2.4 Effectiveness of Procedure

- An ICD is much more effective in treating the condition than a needle decompression.
- The group agrees that this procedure is the best way of managing haemo-, pneumothorax.
- Different techniques like finger sweep thoracenthesis may be as effective, if not more viable pre-hospital.

4.2.5 Skill Level Required to Perform Procedure

- ALS Paramedics are of an adequate skill level to be taught the procedure and to perform it successfully.
- Currently only medical doctors are allowed to perform the procedure.
- Practitioners should be appropriately trained in all aspects of the procedure.
- The skill requires continues monitoring and evaluation.
- The skill is deemed as a 'simple' surgical procedure.

4.2.6 Equipment

- Standard in-hospital equipment should be made available for pre-hospital use.
- Alternative devices like Heimlich valves and purpose bags may be considered appropriate.
- Trochar devices should be avoided.
- All equipment should be provided to meet the need of the procedure.

4.2.7 Other

- Quality assurance, clinical governance, review and skill monitoring should be in place.
- Record keeping and mortality evaluations should be instituted and maintained.

CHAPTER 5

DISCUSSION

5.1 Need for Procedure

Possibly the most important aspect regarding the role of pre-hospital intercostal chest drains would be the need thereof. It would seem fruitless to examine the future usage of a pre-hospital ICD if there is no need for this procedure pre-hospital in South Africa. The literature points out that 25% of all trauma deaths are a result of traumatic thoracic injuries [10 – 15]. In the absence of data regarding the prevalence of chest injuries pre-hospital in South Africa, injuries which might benefit from the treatment with an ICD; we can refer to the anecdotal experience of emergency practitioners. Results from the Delphi study and Focus Group Interview highlight key indicators of the need for the procedure.

Individual Patient Condition

Each incident of chest trauma poses unique factors that contribute to the requirement of an ICD placement. Individual patient condition, coupled with individual circumstances play an intricate role in the determination of the need for pre-hospital ICD. From the 85% of all thoracic traumas that can be treated without specialised surgical intervention [10, 11, 14, 34], the question of risk versus benefit becomes difficult to answer in the broad context. This emphasises the individuality of each patient scenario, and the decisions made by on scene practitioners. Where an ICD is clinically indicated to treat the patient condition, it may limit morbidity and mortality. The experts agree that each scenario should be evaluated individually, and from there a decision reached on the need to place an ICD.

Time to Definitive Care

The geographical size and population makeup of South Africa poses another challenge. Urban areas benefit by having a concentration of emergency services and hospitals in close proximity, which may decrease the time to

definitive care. In the rural areas however, vast distances would have to be covered to reach definitive care, which also increases the time to care. [1] The challenge herein is to balance the capabilities of urban and rural EMS under a national guideline system [26, 31]. This is reflected in the findings of the study where it is agreed that the need for this procedure pre-hospital is not equal between the urban and rural environments.

Definitive care in terms of an ICD placement currently lies within appropriate hospital facilities. The timeous ability to reach these facilities coupled with the patient's condition may determine whether an ICD placement is needed pre-hospital. The generalised 'Golden Hour' is given as a benchmark to work against, whereby the need and benefit of the procedure strongly outweighs the risk where transport times to hospital exceed 60 minutes. As longer time lapse from injury/insult to transport and arrival at hospital, the more a need arises for pre-hospital ICD. It is agreed that an increase in scene time pre-hospital will negatively affect patient outcome. Services should therefore aim to reduce unnecessary time wastage pre-hospital.

Aviation Emergency Medical Care

HEMS in England and Italy have demonstrated the procedure to be safe, effective and improve survival of severe chest injury pre-hospital [47, 50]. Finding from both the Doctors and EMS Delphi groups show strong opinion that there is a need for this procedure in aviation emergency medical care. The reasoning behind this opinion needs further investigation, as there is no current evidence suggesting that South African HEMS systems incorporate this procedure in their daily operations. International success may be a driving factor behind this opinion, which lends to further exploration.

5.2 Safety of Procedure

The term safety can have a variety of implications and understandings when it is related to patient care and management. Whatever the benefit it would bring to the patient comes with risk and possible complication [70]. Many studies have described such complications as insertional, positional and

infective [14, 15, 52 - 54, 60, 65, 70, 71], which may be exacerbated under emergency conditions or by inexperienced practitioners.

Complication Management

A big concern is if complications can be managed successfully in the pre-hospital environment. Strong opinion from both the Delphi and Focus Group Interview suggest that advanced life support (ALS) practitioners are able to manage possible complications appropriately pre-hospital. Although a risk versus benefit analysis would have to be determined on an individual basis, the procedure can be done safely with minimal complications if the correct techniques are applied. To manage an ICD procedure safely, all the possible complications should be mitigated or reduced to an acceptable level.

Procedure Risks

No invasive procedure is without risk, and it is the fine balance of risk versus benefit that contributes to the safety of such procedures. Risks such as inducing a pneumothorax and/or haemothorax or causing uncontrollable bleeding can be limited with appropriate technique, skill, training, equipment and though controlled standard operating procedures. Overall agreement was reached that the use of a traditional Trochar device would increase the risk that could lead to possible complications. Concern was raised regarding the sterility, or clinical cleanliness, of the procedure in the pre-hospital environment.

5.3 Diagnosis of Major Haemo-, Pneumothorax

Diagnosis of conditions requiring possible ICD placement, i.e. pneumothorax and/or haemothorax, is of special concern as it directly attributes to the risk versus benefit analysis. The aetiology [16, 38, 39] of chest injuries together with these conditions associated pathophysiology [16, 38 – 40] leads to distinct clinical features which EMS practitioners are trained in recognising [8, 26, 31].

Clinical Judgement

All practitioners should possess sound clinical judgement when diagnosing pneumothorax and/or haemothorax. Features of these conditions are clinically dramatic and easily recognisable [11, 37], as described by the Royal College of Surgeons of Edinburgh [35]. Large pneumothorax and/or haemothorax will often be life threatening and easily recognisable by ALS practitioners. This substantiates the earlier use of an ICD to prevent further clinical deterioration.

Special Investigations

Investigations like chest X-ray's and Ultrasound are standard practise tools to aid practitioners in their diagnosis of pneumothorax and/or haemothorax. The benefit of such investigations lies within the hospital environment and further assists with diagnosis of minor, or non-immediately life threatening pneumothorax and/or haemothorax, which my not require ICD placement. Pre-hospital practitioners do not have these tools available, nor is it necessary for ICD placement where a life threatening clinical diagnosis is made. Confirmation of placement does however need to be performed by special investigation once the patient has been brought to hospital.

Diagnosis Guidelines

Suitable evidence based guidelines and norms should prevail though pre-hospital clinical diagnosing methods and the use of appropriate diagnosing equipment should be emphasised. Clear indications, standard operating procedures, and clinical guidance will aid pre-hospital practitioners in their diagnosing ability. It may be necessary to combine clinical and special investigation techniques in certain circumstances, which may lead to the development of future pneumothorax and/or haemothorax diagnosing equipment.

5.4 Effectiveness of Procedure

The simplest method of determining the effectiveness of the ICD procedure would be to evaluate the outcome it achieves in the management of the condition it was used for. Initial efficacy can be evaluated almost immediately post placement of an ICD, by the clinical relief of air and/or blood from the pleural space and return of normal intra-pleural pressure [16, 38 – 40]. This procedure performed by skilled medical crews has been shown to decrease mortality in some settings [36, 37]. The more important long term efficacy is however an important aspect to consider.

Long Term Efficacy

The ultimate goal of an ICD placement is to treat the physiological result of a trauma injury sustained to the chest. This is not only limited to immediate and temporary relief, but extends further toward the complete recovery of patients from their insults. Long term efficacy in the pre-hospital environment would have to be through a monitoring perspective in terms of recovery, possible infection acquired and discharge from hospital. The easiest measurement of pre-hospital ICD performance can be viewed against hospital outcomes, which ideally represents definitive care. This can be achieved through various measurement systems and data capturing tools already utilised within hospital environments.

Gold Standard

ICD placement is referred as the 'gold standard' for treating pneumothorax and/or haemothorax in the medical community [19]. Expert opinion regard ICD placement to be superior to the informal needle decompression in the treatment of peumothorax and/or haemothorax, although evidence is lacking with regard to its superiority in the relief of tension pneumothorax and/or haemothorax conditions. Different techniques like finger sweep or simple thoracostomy [36, 53] may be as effective, and may be more viable pre-hospital.

Consultation

Consultation with suitably qualified, experienced and authorised practitioners should be available prior to ICD placement pre-hospital. Appropriate algorithms and strict protocols should be in place to assist pre-hospital practitioners in their diagnosing confidence and procedure performance. The patient should ultimately benefit from the procedure pre-hospital.

5.5 Skill Level Required to Perform Procedure

This heading provided an interesting study phenomenon as none of the statements from Round 1 of the Delphi reached consensus in the following rounds. This is evident from the Doctor's group, the EMS group and the combined expert panel. Only medical doctors are currently trained and permitted to perform an ICD, regarded as a 'simple' surgical procedure, and generally confined to the hospital environment. The pre-hospital environment on the other hand poses various challenges to all levels, especially EMS personnel who are not currently trained or authorised [31] to perform this procedure. This may very well have been the route cause of this uncertainty.

A distinct distribution pattern of tendency was recognised to either agreement or disagreement to some of the statements, which relates to a degree of opinion. The Focus Group Interview also provided some enlightenment en reinforcement to the degree of opinion amongst the experts.

Practitioner Skill Level

It is determined that a practitioner performing and ICD pre-hospital should have a high degree of skill. Disagreement was reached on the statement that 'Only medical doctors should be allowed to perform this procedure pre-hospital'. Emphasis is placed on formal training of the skill to pre-hospital practitioners. Not only on the single skill, but also trained in all aspects of the procedure and possible complications it may have. Continuous monitoring and evaluation should form part of on-going training, with inclusion of ICD placement pre-hospital being utilised selectively by appropriately trained practitioners.

5.6 Equipment

The selection of equipment to perform an ICD procedure may vary according to local product availability, and it is thus difficult to establish a fixed set of equipment regulations. Companies like Portex® and Rocket® have specialised some of their devices for the specific use in ambulatory settings [62 – 64]. Further simplified Heimlich valves or flutter valves [58, 62, 63] have been incorporated in newly improved systems like the Asherman's chest seal [58], which replaces the use of traditional underwater chest drain devices. Widespread agreement between experts is achieved towards common guidelines regarding procedure equipment and monitoring equipment.

Common Guidelines

Equipment for the placement of pre-hospital ICD should be, but not limited to: sterile packaged, sealed, and standardised where possible. Sufficient cleansing solutions should also be available to reduce the risk of introducing infection. Similar equipment to in-hospital ICD packs, and international aeromedical service packs can be used.

Monitoring Equipment

It is recognised that appropriate patient monitoring needs to be done during and post chest drain insertion. Appropriate patient monitors like ECG's oxygen saturation monitors etc., should be available at all times. The use of simplified equipment for pre-hospital ICD insertion should serve as appropriate alternative to bulky instrumentation, e.g. Heimlich valves. Simplified procedure equipment and drainage devices like flutter valves may ultimately prove more suitable for the pre-hospital environment.

5.7 Other

This section did not reveal new opinion to what has already been discussed. Emphasis is however placed on certain areas like skill level, training, clinical governance and record keeping.

Like all advanced procedures, the placement of an ICD is a perishable skill, which requires regular training and skill maintenance, especially if not performed on a regular basis. Any ICD placement in-hospital or pre-hospital requires a practitioner with a high level of skill and current competence in that skill. It is recommended that such training be conducted under the guidance of a suitable medical practitioner, and that integration with hospital units is an essential requirement to maintain pre-hospital practitioner competency.

Clinical governance and quality assurance programs need to be in place to manage the performance of the procedure pre-hospital. Subsequently, an appropriate record of information should be maintained regarding the performance of the procedure pre-hospital. This may serve to continually gather data for evaluating the effectiveness of the procedure. The complications of this procedure as described earlier do not only affect the patient, but uncontrolled pre-hospital conditions may create hazardous complications to the performer of this procedure. Lastly, the need for clinical trails has been raised, which is a standard practise for any procedure to be introduced pre-hospital in South Africa.

5.8 Consensus Strength

A pattern of similar consensus was reached between the two distinct groups of Doctors and EMS within the Delphi study. These consensus reaching statements were augmented by the agreement profiles, as well as through the Focus Group Interview. This strengthens the overall opinion of experts regarding the role of pre-hospital intercostal chest drains in South Africa. Comparison of the findings and opinion against current national and international literature found similar avenues of rationale. This strengthens not only the applicability of the statements to the South African context, but may very well relate and reflect the opinion of the global medical community.

5.9 Limitations of the Study

Delphi Study

This small sample may have introduced bias into the results. Although the sample is less representative than ideal, it still contained a good mixture of different practitioner cadres from across the country. To overcome this anticipated limitation, participant invitations were sent out to as many individuals who conform to the study population as possible. This was achieved utilising various practitioner contact databases, and incorporating internet based social media platforms.

The complexity of the study problem and the diversity of the study population's experience relating to the topic may have contributed to the low rate of consensus. To maximise understanding and to avoid confusion, extensive research information was provided to the individuals prior to their participation. Opinions gathered from Round 1 of the Delphi were carefully synthesised into concise statements to avoid possible misinterpretation.

The majority of the data acquired came from the pre-hospital EMS practitioners, which could have introduced bias in their favour. The inclusion criteria for EMS participants were specifically delineated to reflect a high level of experience and understanding of pre-hospital concepts. However, the similarity in opinion and consensus between the EMS and doctor groups suggest that this bias was minimal.

Focus Group Interview

Limitation of the Focus Group Interview to the Cape Town Metropole confined participation to a small section of the country, and may have introduced bias towards the urban environment. The limited and less representative sample still contained a good mixture of participants whom have working experience throughout the country.

The validity of the Focus Group Interview findings may have been reduced as the participants has not yet achieved the 'reasoned expert' status as defined for the Delphi study. Although not ideal in the generation of individual practitioner opinion, the group's collective opinion strengthens and augments potential individual shortcomings. Comprehension of the study problem was overcome through direct discussion and clarification with the researcher and between individual participants. As a group, the participants were able to generate a collective opinion on the topics of discussion.

CHAPTER 6

CONCLUSION AND RECOMMENDATIONS

6.1 Conclusion

This study has added considerably to the knowledge of practitioner opinion on the feasibility of pre-hospital intercostal chest drains in South Africa. Patient condition and time to definitive care are the most important factors driving the need for the procedure. Practitioners should be able to manage possible complications appropriately pre-hospital. Diagnosing peumothorax and/or haemothorax relies on clinical judgement, and should follow evidence based guidelines and norms. The skill level required performing an ICD procedure, together with the qualification practitioners should hold, remains debated. It is recognised though that not only medical doctors should be able to place ICD's and those practitioners should possess a high level of skill. Equipment to perform the procedure should be standardised, sterile and readily available. Training, clinical governance, record keeping and integration of services remain crucial elements regarding the performance of the procedure pre-hospital.

6.2 Recommendations

The aim of the study was to identify practitioner thoughts and feelings' regarding the potential role of pre-hospital intercostal chest drains in South Africa. Through delineation of the topic and the establishment of specific defining headings, this role has been enlightened through the description of opinions from experts in the field of emergency medical care. The findings of the study coupled with the knowledge gained through the literature review produces key recommendations for future research and the implementation of intercostal chest drains pre-hospital in South Africa.

6.2.1 Establishment of the Need

To establish the need for this procedure pre-hospital, certain key elements would have to be investigated further:

- Incidence of chest trauma requiring the use of an ICD.
- A comparison between the urban and rural pre-hospital emergency care environments relating to chest trauma.
- Analysis of pre-hospital scene and transport times to definitive care.
- The use of ICD's in aviation emergence medical care.

6.2.2 Evaluation of the Safety

The unique nature of a pre-hospital setting provides challenges related to the safety of the procedure in conducted in this environment. It is thus crucial to evaluate and question the safety of this procedure pre-hospital:

- What are the elements that contribute to safety in the pre-hospital environment?
- How can complications of an ICD be mitigated pre-hospital?
- What are the risks to the patient and the practitioner when performing this procedure in the pre-hospital environment?

6.2.3 Diagnosis and Skill Level Requirements

Diagnosis of major haemo-, pneumothorax can be coupled with the skill level required to perform the procedure, as both elements require a high level of practitioner competency:

- Pre-hospital EMS practitioner capability to diagnose these conditions should be evaluated.
- Their ability to perform the procedure should also be evaluated.
- Comparison between clinical diagnosing techniques and special investigations should be carried out to determine the level of accuracy and dependability of clinical abilities.

6.2.4 Effectiveness

It has been established that ICD placement for the management of pneumothorax and/or haemothorax remains the 'gold standard' of care:

- Investigation into long term efficacy should be explored to establish the benefit chest injury patients will gain from earlier pre-hospital ICD placement.
- Comparison studies should be carried out to determine the value of pre-hospital ICD compared to traditional needle decompression.

6.2.5 Implementation

To implement the use of pre-hospital ICD's in South Africa, it would be necessary to conduct clinical trials:

- The scope of the clinical trials would have to be established, incorporating scientific evidence already identified.
- Emphasis should be placed on training, clinical governance and quality assurance.
- The 'scope of practise' of advanced EMS practitioners should be extended accordingly.
- Integration of various health systems has to be done in conjunction with the support of local and national health/EMS departments, medical education institutions, and regulating authorities.

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(APPENDIX1) –
Research Participation
Invitation

RESEARCH PARTICIPATION INVITATION

UNIVERSITY:	University of Cape Town (UCT)
FACULTY:	Health Sciences
DIVISION:	Emergency Medicine
STUDENT:	Mr Enrico Dippenaar (DPPENR001)
EMAIL ADDRESS:	edippenaar@mweb.co.za
CONTACT NUMBER:	083 585 1888
SUPERVISOR:	Professor Lee Wallis
EMAIL ADDRESS:	leewallis@bvr.co.za
CONTACT NUMBER:	021 – 948 9908
ETHICAL APPROVAL REFERENCE:	HREC REF: 317/2012

To whom it may concern:

I am conducting a research study towards complete fulfilment of a Masters of Science Degree in Emergency Medicine at the University of Cape Town; with the following Title, Aim, Objectives and Inclusion Criteria:

Title

Identifying the role of pre-hospital intercostal chest drains in South Africa

Aim

Highlight issues regarding the placement of intercostal chest drains in the pre-hospital environment in South Africa.

Objectives

Conduct a National modified Delphi study followed by regional focus group interviews within the Western Cape; by grouping emergency centre

specialists (emergency medicine specialists and trauma surgeons) – group 1, and emergency medical services (emergency care practitioners and paramedics) – group 2.

Identify key issues of relevance to the question of whether intercostal chest drains (ICD's) have a role in the pre-hospital environment in South Africa, and the current opinion of this role amongst South African emergency care experts.

The issues that are expanded upon by the South African experts will be reflected in recommendations, aimed at hypothesis and idea generation for potential future research, and policy development.

Inclusion Criteria

Group 1:

- Emergency Physicians/Specialists
- Trauma Surgeons

Group 2:

- Registered Emergency Care Practitioners (ECP register), with more than five years' experience within Emergency Medical Services (EMS), at an advanced life support level.
- Registered Paramedics (ANT register) with more than seven years' experience within Emergency Medical Services (EMS), at an advanced life support level.

I hereby cordially invite practitioners, who meet the study Inclusion Criteria, to participate in this research study. Participation is completely voluntary and will consist of email and internet based correspondence during the Delphi process, after which invitations to participate in Western Cape focus group interviews will be conveyed. Your participation will be greatly appreciated and add value to the development of the emergency care profession.

To participate in this study, and/or to receive further information, please contact the investigator (student) via the contact details provided above.

Regards

Enrico Dippenaar

(APPENDIX 2) – Round 1 Delphi Questionnaire

(Copied from 'SurveyMonkey®' '.pdf')

Identifying the role of pre-hospital intercostal chest drains in South Afri...

Thank you for taking time to participate in this study. It is understood that you have familiarised yourself with the study information leaflet and completed the relevant consent form.

The first round of the Delphi will consist of gathering your expert opinion, through statements and/or comments, regarding the placement of pre-hospital intercostal chest drains in South Africa.

On the next page you will find seven headings under which you may provide your statements and/or comments. The information provided in brackets may serve to guide, but not limit, your thought process. Also note that you are not limited to the size of each input box, they will scroll down as you provide further input.

For ease of study process, please attempt to keep your statements and/or comments as concise as possible.

Should you have any further questions, you may contact the principle investigator, Enrico Dippenaar at: edippenaar@mweb.co.za

The first four questions on this page is compulsory for study purposes.

***1. Name and Surname:**

***2. HPCSA Registration Number:**

***3. Under which practice field or speciality are you registered:**

- ◯ Trauma Surgeon
- ◯ Emergency Physician
- ◯ Paramedic (ANT)
- ◯ Emergency Care Practitioner (ECP)

***4. I hereby acknowledge and consent to my participation in this study.**

- ◯ YES
- ◯ NO

Delphi Round 1

1. Need for Procedure (Urban vs. Rural, Public vs. Private)

2. Safety of Procedure (Risk/Complications vs. Benefit/Improved Patient Outcomes)

3. Diagnosis of major haemo-, pneumothoraces (Indications, Contraindications, Methods of Clinical Diagnosis)

4. Effectiveness of procedure (Treatment of Injury, Patient outcome measures)

5. **Skill level required to perform procedure (Medical Doctors, Emergency Care Practitioners (Degree qualified), Paramedics (CCA or N.Dip qualified))**

6. **Equipment (Required and/or Available to perform procedure)**

7. **Other (Any other issues regarding the placement of pre-hospital intercostal chest drains in South Africa)**

(APPENDIX 3) – Round 1 Delphi Synthesis

DELPHI ROUND 1 SYNTHESIS FINAL

1. NEED FOR PROCEDURE *(Urban vs. Rural, Public vs. Private)*
• There is a need for this procedure in the pre-hospital urban environment.
• There is a need for this procedure in the pre-hospital rural environment.
• The need for this procedure in the pre-hospital urban and rural environments is equal.
• There is a need for this procedure in the pre-hospital private sector.
• There is a need for this procedure in the pre-hospital public sector.
• The need for this procedure in the pre-hospital private and public sectors is equal.
• The need for this procedure increases in overloaded medical systems.
• The patient's condition determines the need for this procedure pre-hospital.
• The time from pre-hospital to hospital determines the pre-hospital need for this procedure.
• The distance from pre-hospital to hospital determines the pre-hospital need for this procedure.
• There is a need for this procedure where transport times to hospital exceed 30 minutes.
• There is a need for this procedure where transport times to hospital exceed 60 minutes.
• It would benefit patients if there are more providers of this procedure pre-hospital.
• There is a need for this procedure pre-hospital for prolonged entrapped patients when indicated.
• Patients will benefit greatly if this procedure is performed earlier.
• There is a need for this procedure pre-hospital where indicated in cardio-pulmonary resuscitation.

• There is a need for this procedure in aviation emergency medical care.
• Where clinically indicated, this procedure limits morbidity and mortality.
• Further studies are required to determine the need for this procedure pre-hospital.
2. SAFETY OF PROCEDURE *(Risk/Complications vs. Benefit/Improved Patient Outcomes)*
• The benefit of this procedure pre-hospital outweighs the risk.
• The risk of infection outweighs the benefit of this procedure pre-hospital.
• The risk of infection from this procedure pre-hospital can be suitably treated in-hospital.
• Complications of this procedure pre-hospital can be suitably treated in-hospital.
• Complications of this procedure pre-hospital can be limited by appropriate technique.
• Practitioners should be able to manage possible complications appropriately pre-hospital.
• This procedure has been seen performed successfully pre-hospital.
• Patients seen treated with this procedure pre-hospital have benefitted greatly.
• This procedure performed pre-hospital has shown minimal complications.
• This procedure should be limited to controlled environments.
• This procedure has shown improved patient clinical outcome in-hospital.
• There is an increased risk using a Trochar device in performance of this procedure.
• With appropriate training, this procedure should be safe when indicated pre-hospital.
• There will be an increase in scene time if this procedure is performed pre-hospital.
• An increase in scene time pre-hospital will negatively affect patient outcome.
• Patients need to be transported rapidly to a hospital facility following this procedure.
• This procedure can be done safely pre-hospital if practitioners are adequately trained.

• This procedure can be done safely pre-hospital if practitioners are adequately equipped.
• This procedure pre-hospital has the risk of introducing a haemothorax.
• This procedure pre-hospital has the risk of introducing a pneumothorax.
• Draining a large haemothorax pre-hospital may lead to uncontrollable bleeding.
• This procedure pre-hospital would be purposeless where a patient requires a thoracotomy.
• Where this procedure is clinically indicated it will potentially benefit peri-arrest patients.
• This procedure performed pre-hospital will allow practitioners to successfully manage haemothorax.
• This procedure performed pre-hospital will allow practitioners to successfully manage pneumothorax.
• Pre-hospital practitioners will be able to maintain the required skill to perform procedure.
3. DIAGNOSIS OF MAJOR HAEMO-, PNEUMOTHORACES *(Indications, Contraindications, Methods of Clinical Diagnosis)*
• Diagnosis of major haemothorax should only be clinical.
• Diagnosis of major pneumothorax should only be clinical.
• Practitioners should possess sound clinical judgement when diagnosing haemothorax.
• Practitioners should possess sound clinical judgement when diagnosing pneumothorax.
• Suitable pre-hospital clinical diagnosing methods should be utilised when diagnosing haemothorax.
• Suitable pre-hospital clinical diagnosing methods should be utilised when diagnosing pneumothorax.

• Suitable pre-hospital clinical diagnosing equipment should be utilised when diagnosing haemothorax.
• Suitable pre-hospital clinical diagnosing equipment should be utilised when diagnosing pneumothorax.
• A combination of clinical and special investigations should be utilised when diagnosing haemothorax.
• A combination of clinical and special investigations should be utilised when diagnosing pneumothorax.
• This procedure should only be done after X-ray diagnosis confirmation.
• X-ray diagnosis and placement confirmation should be done after the procedure.
• This procedure can be performed if diagnosing haemothorax is limited to clinical investigations.
• This procedure can be performed if diagnosing pneumothorax is limited to clinical investigations.
• If a needle thoracenthesis is indicated, so is this procedure.
• This procedure should be limited to patients who are in immediate clinical danger.
• Large haemothorax will not often be life threatening.
• Large pneumothorax will not often be life threatening.
• A massive pneumothorax has a low risk of tensioning if the patient is not positively pressure ventilated.
• A tension pneumothorax must first be needle decompressed before attempting this procedure.
• This procedure requires extensive patient monitoring.
• Ultrasound is the method of choice for pre-hospital diagnosing of haemothorax.
• Ultrasound is the method of choice for pre-hospital diagnosing of pneumothorax.
• Evidence based guidelines and norms should apply when diagnosing haemothorax pre-hospital.

• Evidence based guidelines and norms should apply when diagnosing pneumothorax pre-hospital.
4. EFFECTIVENESS OF PROCEDURE *(Treatment of Injury, Patient Outcome Measures)*
• This procedure is the gold standard for treating haemothorax.
• This procedure is the gold standard for treating pneumothorax.
• Where indicated pre-hospital, this procedure will improve patient outcome.
• This procedure performed pre-hospital will improve long-term patient outcome.
• This procedure is effective if performed correctly pre-hospital.
• Pre-hospital effectiveness of this procedure is difficult to measure.
• Pre-hospital outcomes of this procedure should be measured against hospital outcomes.
• There is a high morbidity from incorrect procedure placement pre-hospital.
• Pre-hospital procedure efficacy can be assessed clinically.
• This procedure is more effective than an informal needle decompression.
• Long term efficacy of this procedure pre-hospital need to be through a monitoring perspective (in terms of infection and discharge from hospital).
• Appropriate algorithms will guide practitioners to perform this procedure effectively pre-hospital.
• Strict protocols need to be in place to ensure that patients' ultimately benefit from this procedure pre-hospital.
• Consultation with suitable practitioners should be available prior to performing this procedure pre-hospital.
• Consultation with suitable practitioners should be mandatory prior to performing this procedure pre-hospital.

5. SKILL LEVEL REQUIRED TO PERFORM PROCEDURE *(Medical Doctors, Emergency Care Practitioners (Degree qualified), Paramedics (CCA or N.Dip qualified)*
• Only medical doctors should be allowed to perform this procedure pre-hospital.
• Medical doctors with ED or surgical experience are preferred to perform this procedure pre-hospital.
• Specially trained professional nurses should be allowed to perform this procedure pre-hospital.
• Emergency Care Practitioners (Degree qualified) with appropriate training should be allowed to perform this procedure pre-hospital.
• All advanced life support practitioners with appropriate training should be allowed to perform this procedure pre-hospital.
• All skill levelled practitioners can be trained to perform this procedure pre-hospital.
• Mature and experienced practitioners are preferred to perform this procedure pre-hospital.
• A high skill levelled practitioner is required to perform this procedure pre-hospital.
• This procedure can be successfully performed by a single practitioner.
• The performance of this procedure pre-hospital should form part of formal training.
• This procedure can be selectively utilised pre-hospital by appropriately trained practitioners.
6. EQUIPMENT *(Required and/or Available to Perform Procedure)*
• All equipment used during this procedure pre-hospital should be sterile packaged.
• Pre-packaged kits should be available to perform this procedure pre-hospital.
• All kits used during this procedure pre-hospital should be sealed.
• All kits used during this procedure pre-hospital should be standardised.

• Appropriate equipment to perform this procedure pre-hospital is not currently available.
• Similar equipment utilised in-hospital to perform this procedure should be utilised pre-hospital.
• Similar equipment utilised on aeromedical services to perform this procedure should be utilised pre-hospital.
• Sufficient cleansing solutions need to be utilised to reduce the risk of infection.
• Appropriate monitoring equipment should be utilised to evaluate a patient's condition during performance of this procedure.
• Alternative drainage devices are available to suit the pre-hospital environment.
• Simplified procedure equipment can be utilised to suit the pre-hospital environment.
• Simplified drainage devices can be utilised to suit the pre-hospital environment.
7. OTHER *(Any other issues regarding the placement of pre-hospital intercostal chest drains in South Africa)*
• There is no need for this procedure pre-hospital in South Africa.
• This procedure will lead to unnecessarily long pre-hospital scene time.
• There is a big risk of misdiagnosing haemothorax pre-hospital.
• There is a big risk of misdiagnosing pneumothorax pre-hospital.
• A tension pneumothorax can be successfully managed with a needle decompression pre-hospital.
• This procedure can be a module as part of the emergency care practitioner training.
• Practitioners will have to maintain a high skill level to perform this procedure pre-hospital.
• Integration with hospital trauma units is required to maintain practitioner competency in the performance of this procedure pre-hospital.

• Regular training and skill maintenance of this procedure pre-hospital is required to maintain practitioner competency.
• Training of this procedure pre-hospital should be conducted under the guidance of a suitable medical practitioner.
• This procedure can be performed in transit.
• Clinical governance and quality assurance need to be in place to manage the performance of this procedure pre-hospital.
• A good record of information should be maintained regarding the performance of this procedure pre-hospital.
• Uncontrolled conditions pre-hospital create hazardous complications to the performer of this procedure.
• Clinical trails need to be carried out to establish the efficacy of this procedure pre-hospital.

(APPENDIX 4) – Round 2 Delphi Questionnaire *(Copied from 'SurveyMonkey®,'.pdf')*

Identifying the role of pre-hospital intercostal chest drains in South Afri...

Thank you for taking time to participate in this study. It is understood that you have familiarized yourself with the study information leaflet, completed and sent back the relevant consent form. At this stage of the study, all participants from round one, as well as any new participant (who meet the participant inclusion criteria) are urged to complete this survey.

This second round of the National Delphi will consist of rating the statements collected from round one. The rating system consists of a ranking from 1 - 9, whereby:

1 - 2 : Strongly Disagree
3 - 4 : Disagree
5 : Neither Agree nor Disagree
6 - 7 : Agree
8 - 9 : Strongly Agree

On the next page you will find each statement heading with its related statements. Please tick your desired Agreement or Disagreement with the statement provided.

Note: The term "this/the Procedure" refers to Intercostal Chest Drain placement.

Should you have any further questions, you may contact the principle investigator, Enrico Dippenaar at edippenaar@uwc.ac.za

The first four questions on this page is compulsory for study purposes, the second page contains all the statement fields.

Please complete all the questions, you may return to your unique survey at any time during the second round period. This can be done through your emailed link, which is unique to you, to complete, finalize or change your input at any time.

Press the next tab at the bottom of the page to go to the second page, and done when you have completed the survey.

***1. Name and Surname:**

***2. HPCSA Registration Number:**

*** 3. Under which practise field or speciality are you registered:**

- ◯ Trauma surgeon
- ◯ Emergency Physician
- ◯ Paramedic (ANT)
- ◯ Emergency Care Practitioner (ECP)

*** 4. I hereby acknowledge and consent to my participation in this study:**

- ◯ YES
- ◯ NO

Delphi Round 2

1 - 2 : Strongly Disagree
3 - 4 : Disagree
5 : Neither Agree nor Disagree
6 - 7 : Agree
8 - 9 : Strongly Agree

Note: The term "this/the Procedure" refers to Intercostal Chest Drain placement

1. NEED FOR PROCEDURE

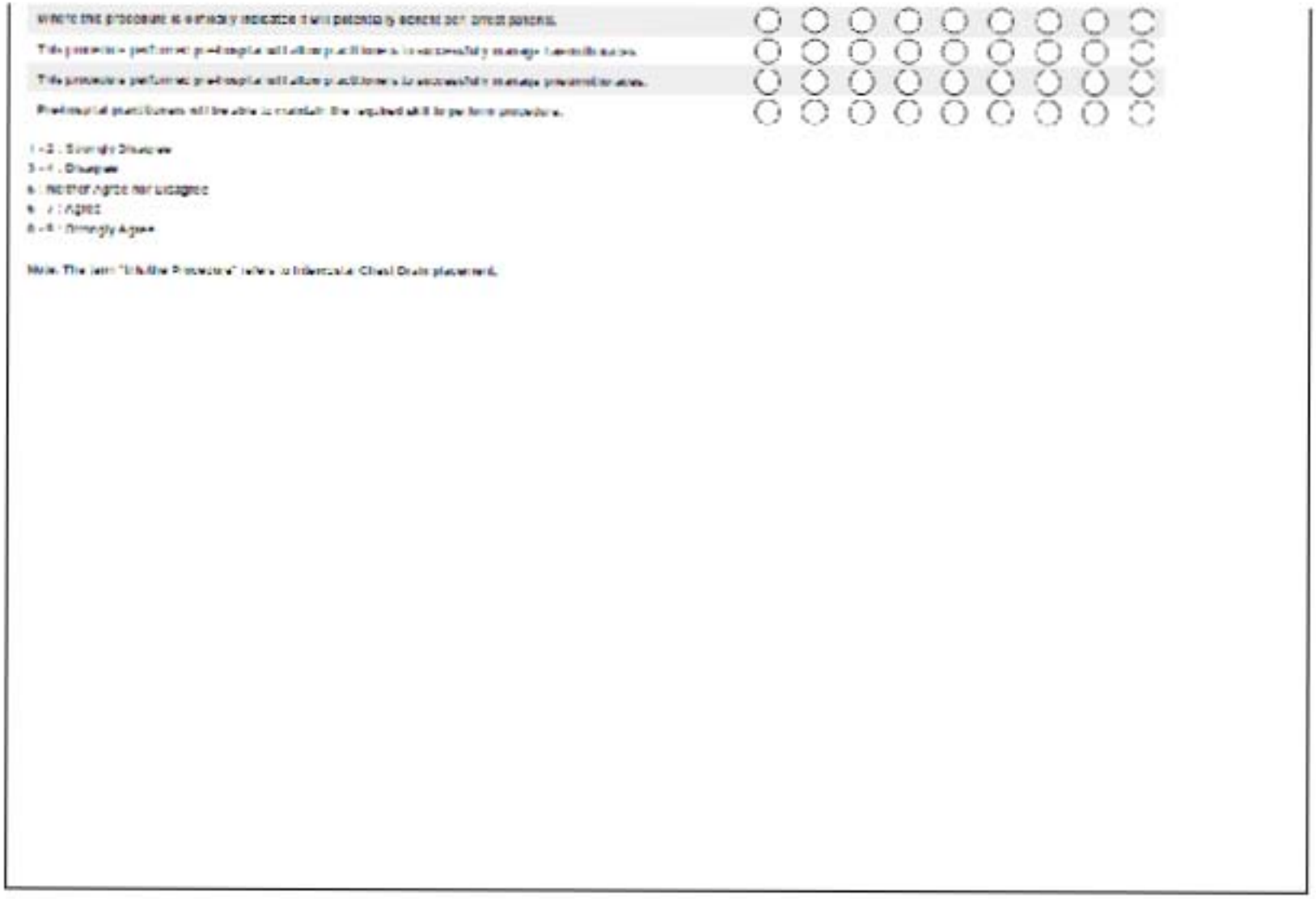
	1	2	3	4	5	6	7	8	9
There is a need for this procedure in the pre-hospital urban environment.	○	○	○	○	○	○	○	○	○
There is a need for this procedure in the pre-hospital rural environment.	○	○	○	○	○	○	○	○	○
The need for this procedure in the pre-hospital urban and rural environments is equal.	○	○	○	○	○	○	○	○	○
There is a need for this procedure in the pre-hospital private sector.	○	○	○	○	○	○	○	○	○
There is a need for this procedure in the pre-hospital public sector.	○	○	○	○	○	○	○	○	○
The need for this procedure in the pre-hospital private and public sectors is equal.	○	○	○	○	○	○	○	○	○
The need for this procedure increases in overloaded medical systems.	○	○	○	○	○	○	○	○	○
The patients condition determines the need for this procedure pre-hospital.	○	○	○	○	○	○	○	○	○
The time from pre-hospital to hospital determines the pre-hospital need for this procedure.	○	○	○	○	○	○	○	○	○
The distance from pre-hospital to hospital determines the pre-hospital need for this procedure.	○	○	○	○	○	○	○	○	○
There is a need for this procedure where transport times to hospital exceed 60 minutes.	○	○	○	○	○	○	○	○	○
There is a need for this procedure where transport times to hospital exceed 60 minutes.	○	○	○	○	○	○	○	○	○
It would benefit patients if there are more providers of this procedure pre-hospital.	○	○	○	○	○	○	○	○	○
There is a need for this procedure pre-hospital for prolonged entrapped patients when indicated.	○	○	○	○	○	○	○	○	○
Patients will benefit greatly if this procedure is performed earlier.	○	○	○	○	○	○	○	○	○
There is a need for this procedure pre-hospital where indicated in cardiopulmonary resuscitation.	○	○	○	○	○	○	○	○	○
There is a need for this procedure in aviation emergency medical care.	○	○	○	○	○	○	○	○	○
Where clinically indicated, this procedure limits morbidity and mortality.	○	○	○	○	○	○	○	○	○
Further studies are required to determine the need for this procedure pre-hospital.	○	○	○	○	○	○	○	○	○

1 - 3 : Strongly Disagree
4 : Disagree
5 : Neither Agree nor Disagree
6 - 7 : Agree
8 - 9 : Strongly Agree

Note: the term 'intubation' refers to intubation under direct vision

2. SAFETY OF PROCEDURE

	1	2	3	4	5	6	7	8	9
The benefit of this procedure pre-hospital outweighs the risk	○	○	○	○	○	○	○	○	○
The risk of infection outweighs the benefit of this procedure pre-hospital	○	○	○	○	○	○	○	○	○
The risk of infection from this procedure pre-hospital can be suitably treated in-hospital.	○	○	○	○	○	○	○	○	○
Complications of this procedure pre hospital can be suitably treated in-hospital.	○	○	○	○	○	○	○	○	○
Complications of this procedure pre hospital can be limited by appropriate technique.	○	○	○	○	○	○	○	○	○
Practitioners should be able to manage possible complications appropriately pre-hospital	○	○	○	○	○	○	○	○	○
This procedure has been safely performed successfully pre-hospital	○	○	○	○	○	○	○	○	○
Treating poor fracture with this procedure pre hospital is not associated greatly	○	○	○	○	○	○	○	○	○
This procedure performed pre hospital has shown minimal complications.	○	○	○	○	○	○	○	○	○
This procedure should be limited to controlled environments.	○	○	○	○	○	○	○	○	○
This procedure has shown improved patient clinical outcome in-hospital.	○	○	○	○	○	○	○	○	○
There is an increased risk using a Trocar device in performance of this procedure.	○	○	○	○	○	○	○	○	○
With appropriate training, this procedure should be safe when indicated pre-hospital.	○	○	○	○	○	○	○	○	○
There will be an increase in scene time if this procedure is performed pre-hospital	○	○	○	○	○	○	○	○	○
An increase in scene time pre-hospital will negatively affect patient outcome	○	○	○	○	○	○	○	○	○
Patients need to be transported rapidly to a hospital shortly following this procedure.	○	○	○	○	○	○	○	○	○
This procedure can be done safely pre-hospital if practitioners are adequately trained	○	○	○	○	○	○	○	○	○
This procedure can be done safely pre-hospital if practitioners are adequately equipped	○	○	○	○	○	○	○	○	○
This procedure pre-hospital has the risk of introducing a haemothorax.	○	○	○	○	○	○	○	○	○
This procedure pre-hospital has the risk of introducing a pneumothorax.	○	○	○	○	○	○	○	○	○
Draining a large haemothorax pre hospital may lead to uncontrollable bleeding.	○	○	○	○	○	○	○	○	○
This procedure pre-hospital should be purposeless where a patient requires a thoracotomy	○	○	○	○	○	○	○	○	○



3. DIAGNOSIS OF MAJOR HAEMO-, PNEUMOTHORACES

	1	2	3	4	5	6	7	8	9
Diagnosis of major haemothoraces should only be clinical.	○	○	○	○	○	○	○	○	○
Diagnosis of major pneumothoraces should only be clinical.	○	○	○	○	○	○	○	○	○
Practitioners should possess sound clinical judgement when diagnosing haemothoraces.	○	○	○	○	○	○	○	○	○
Practitioners should possess sound clinical judgement when diagnosing pneumothoraces.	○	○	○	○	○	○	○	○	○
Suitable pre-hospital clinical diagnostic methods should be utilized when diagnosing haemothoraces.	○	○	○	○	○	○	○	○	○
Suitable pre-hospital clinical diagnostic methods should be utilized when diagnosing pneumothoraces.	○	○	○	○	○	○	○	○	○
Suitable pre-hospital clinical diagnostic equipment should be utilized when diagnosing haemothoraces.	○	○	○	○	○	○	○	○	○
Suitable pre-hospital clinical diagnostic equipment should be utilized when diagnosing pneumothoraces.	○	○	○	○	○	○	○	○	○
A combination of clinical and special investigations should be utilized when diagnosing haemothoraces.	○	○	○	○	○	○	○	○	○
A combination of clinical and special investigations should be utilized when diagnosing pneumothoraces.	○	○	○	○	○	○	○	○	○
This procedure should only be done after X-ray diagnosis confirmation.	○	○	○	○	○	○	○	○	○
X-ray diagnosis and placement confirmation should be done after the procedure.	○	○	○	○	○	○	○	○	○
This procedure can be performed if diagnosis haemothoraces is limited to clinical investigations.	○	○	○	○	○	○	○	○	○
This procedure can be performed if diagnosis pneumothoraces is limited to clinical investigations.	○	○	○	○	○	○	○	○	○
If a needle thoracentesis is indicated, do so this procedure.	○	○	○	○	○	○	○	○	○
This procedure should be limited to patients who are in immediate clinical danger.	○	○	○	○	○	○	○	○	○
Large haemothoraces will not often be life threatening.	○	○	○	○	○	○	○	○	○
Large pneumothoraces will not often be life threatening.	○	○	○	○	○	○	○	○	○
A massive pneumothorax has a low risk of tensioning if the patient is not positively pressure ventilated.	○	○	○	○	○	○	○	○	○
A tension pneumothorax must first be needle decompressed before attempting this procedure.	○	○	○	○	○	○	○	○	○
This procedure requires extensive patient monitoring.	○	○	○	○	○	○	○	○	○
Ultrasound is the method of choice for pre-hospital diagnosing of haemothoraces.	○	○	○	○	○	○	○	○	○
Ultrasound is the method of choice for pre-hospital diagnosing of pneumothoraces.	○	○	○	○	○	○	○	○	○
Evidence based guidelines and norms should apply when diagnosing haemothoraces pre-hospital.	○	○	○	○	○	○	○	○	○
Evidence based guidelines and norms should apply when diagnosing pneumothoraces pre-hospital.	○	○	○	○	○	○	○	○	○

1 - 2 : Strongly Disagree
3 - 4 : Disagree
5 : Neither Agree nor Disagree
6 - 7 : Agree
8 - 9 : Strongly Agree

Note: The term "this/the Procedure" refers to Intercostal Chest Drain placement

4. EFFECTIVENESS OF PROCEDURE

	1	2	3	4	5	6	7	8	9
This procedure is the gold standard for treating haemothorax.	○	○	○	○	○	○	○	○	○
This procedure is the gold standard for treating pneumothorax.	○	○	○	○	○	○	○	○	○
Where indicated pre-hospital, this procedure will improve patient outcome.	○	○	○	○	○	○	○	○	○
This procedure performed pre-hospital will improve long-term patient outcome.	○	○	○	○	○	○	○	○	○
This procedure is effective if performed correctly pre-hospital.	○	○	○	○	○	○	○	○	○
The hospital effectiveness of this procedure is difficult to measure.	○	○	○	○	○	○	○	○	○
The hospital outcomes of this procedure should be measured against hospital outcomes.	○	○	○	○	○	○	○	○	○
There is a high morbidity from incorrect procedure placement pre-hospital.	○	○	○	○	○	○	○	○	○
Pre-hospital procedure efficacy can be assessed clinically.	○	○	○	○	○	○	○	○	○
This procedure is more effective than an internal needle decompression.	○	○	○	○	○	○	○	○	○
Long term efficacy of this procedure pre-hospital need to be through a monitoring perspective (in terms of infection and discharge from hospital).	○	○	○	○	○	○	○	○	○
Appropriate algorithms will guide practitioners to perform this procedure effectively pre-hospital.	○	○	○	○	○	○	○	○	○
Strict protocols need to be in place to ensure that patients ultimately benefit from this procedure pre-hospital.	○	○	○	○	○	○	○	○	○
Consultation with suitable practitioners should be available prior to performing this procedure pre-hospital.	○	○	○	○	○	○	○	○	○
Consultation with suitable practitioners should be mandatory prior to performing this procedure pre-hospital.	○	○	○	○	○	○	○	○	○

1 - 2 : Strongly Disagree
3 - 4 : Disagree
5 : Neither Agree nor Disagree
6 - 7 : Agree
8 - 9 : Strongly Agree

Note: The term "this/the Procedure" refers to Intercostal Chest Drain placement

5. SKILL LEVEL REQUIRED TO PERFORM PROCEDURE

	1	2	3	4	5	6	7	8	9
Only medical doctors should be allowed to perform this procedure pre-hospital.	○	○	○	○	○	○	○	○	○
Medical doctors with ED or surgical experience are preferred to perform this procedure pre hospital.	○	○	○	○	○	○	○	○	○
Specially trained professional nurses should be allowed to perform this procedure pre-hospital.	○	○	○	○	○	○	○	○	○
Emergency Care Practitioners (Degree qualified) with appropriate training should be allowed to perform this procedure pre-hospital	○	○	○	○	○	○	○	○	○
All advanced life support practitioners with appropriate training should be allowed to perform this procedure pre hospital.	○	○	○	○	○	○	○	○	○
All skill levelled practitioners can be trained to perform this procedure pre-hospital.	○	○	○	○	○	○	○	○	○
Mature and experienced practitioners are preferred to perform this procedure pre-hospita	○	○	○	○	○	○	○	○	○
A high skill levelled practitioner is required to perform this procedure pre-hospital.	○	○	○	○	○	○	○	○	○
This procedure can be successfully performed by a single practitioner.	○	○	○	○	○	○	○	○	○
The performance of this procedure pre hospital should form part of formal training.	○	○	○	○	○	○	○	○	○
This procedure can be selectively utilised pre-hospitally by appropriately trained practitioners	○	○	○	○	○	○	○	○	○

1 - 2 : Strongly Disagree
3 - 4 : Disagree
5 : Neither Agree nor Disagree
6 - 7 : Agree
8 - 9 : Strongly Agree

Note: The term "this procedure" refers to intercostal chest drain placement.

6. EQUIPMENT

	1	2	3	4	5	6	7	8	9
All equipment used during this procedure pre-hospital should be sterile packaged.	○	○	○	○	○	○	○	○	○
Pre packaged kits should be available to perform this procedure pre hospital.	○	○	○	○	○	○	○	○	○
All kits used during this procedure pre-hospital should be sealed.	○	○	○	○	○	○	○	○	○
All kits used during this procedure pre-hospital should be standardised.	○	○	○	○	○	○	○	○	○
Appropriate equipment to perform this procedure pre-hospital is not currently available.	○	○	○	○	○	○	○	○	○
Similar equipment utilized in hospital to perform this procedure should be utilized pre hospital.	○	○	○	○	○	○	○	○	○
Similar equipment utilized on aeromedical services to perform this procedure should be utilized pre hospital.	○	○	○	○	○	○	○	○	○
Sufficient cleansing solutions need to be utilized to reduce the risk of infection.	○	○	○	○	○	○	○	○	○
Appropriate monitoring equipment should be utilized to evaluate a patient's condition during performance of this procedure.	○	○	○	○	○	○	○	○	○
Alternative drainage devices are available to suit the pre-hospital environment.	○	○	○	○	○	○	○	○	○
Simplified procedure equipment can be utilized to suit the pre-hospital environment.	○	○	○	○	○	○	○	○	○
Similar drainage devices can be utilized to suit the pre hospital environment.	○	○	○	○	○	○	○	○	○

1 - 2 : Strongly Disagree
3 - 4 : Disagree
5 : Neither Agree nor Disagree
6 - 7 : Agree
8 - 9 : Strongly Agree

Note. The term "Tube Procedure" refers to Intercostal Chest Drain placement.

7. OTHER

	1	2	3	4	5	6	7	8	9
There is no need for this procedure pre-hospital in South Africa.	○	○	○	○	○	○	○	○	○
This procedure will lead to unnecessarily long pre hospital scene time.	○	○	○	○	○	○	○	○	○
There is a big risk of misdiagnosing haemothraces pre-hospital.	○	○	○	○	○	○	○	○	○
There is a big risk of misdiagnosing pneumothraces pre-hospital	○	○	○	○	○	○	○	○	○
A tension pneumothorax can be successfully managed with a needle decompression pre-hospital.	○	○	○	○	○	○	○	○	○
This procedure can be a module as part of the emergency care practitioner training.	○	○	○	○	○	○	○	○	○
Practitioners will have to maintain a high skill level to perform this procedure pre hospital.	○	○	○	○	○	○	○	○	○
Integration with hospital trauma units is required to maintain practitioner competency in the performance of this procedure pre-hospital	○	○	○	○	○	○	○	○	○
Regular training and skill maintenance of this procedure pre-hospital is required to maintain practitioner competency.	○	○	○	○	○	○	○	○	○
Training of this procedure pre-hospital should be conducted under the guidance of a suitable medical practitioner	○	○	○	○	○	○	○	○	○
This procedure can be performed in transit.	○	○	○	○	○	○	○	○	○
Clinical governance and quality assurance need to be in place to manage the performance of this procedure pre-hospital.	○	○	○	○	○	○	○	○	○
A good record of information should be maintained regarding the performance of this procedure pre-hospital.	○	○	○	○	○	○	○	○	○
Uncontrolled conditions pre hospital create hazardous complications to the performer of this procedure	○	○	○	○	○	○	○	○	○
Clinical trails need to be carried out to establish the efficacy of this procedure pre-hospital.	○	○	○	○	○	○	○	○	○

(APPENDIX 5) – Round 3 Delphi Questionnaire *(Microsoft Excel® Spreadsheet)*

INTERCOSTAL CHEST DRAIN DELPHI - ROUND 3

Welcome to the 3rd round of the Intercostal Chest Drain Delphi. The purpose of this 3rd and final round is to create a stronger consensus on the rated statements from the 2nd round. In this round you have the option to re-evaluate your rating selection in light of the calculated trend of all the participants. On review of the statements, you may choose to keep or change your rating.

* If you choose to **keep** your rating selection from the 2nd round, please leave the re-evaluation coulomb **BLANK**.
* If you choose to **change** your rating selection, please **ENTER THE NUMBER** accordingly in the re-evaluation coulomb.

1. NEED FOR PROCEDURE: *(Urban vs. Rural, Public vs. Private)*	**TREND**	**YOUR RATING**	**RE-EVALUATION**
| 1 2 | 3 4 | 5 | 6 7 | 8 9 |			
Strongly Disagree — Disagree — Neither Agree nor Disagree — Agree — Strongly Agree			
There is a need for this procedure in the pre-hospital urban environment.	Strongly Disagree		
There is a need for this procedure in the pre-hospital rural environment.	Strongly Agree		
The need for this procedure in the pre-hospital urban and rural environments is equal.	Disagree		
There is a need for this procedure in the pre-hospital private sector.	Agree		
There is a need for this procedure in the pre-hospital public sector.	Agree		
The need for this procedure in the pre-hospital private and public sectors is equal.	Strongly Agree		
The need for this procedure increases in overloaded medical systems.	Agree		
The patient's condition determines the need for this procedure pre-hospital.	Strongly Agree		
The time from pre-hospital to hospital determines the pre-hospital need for this procedure.	Strongly Agree		
The distance from pre-hospital to hospital determines the pre-hospital need for this procedure.	Strongly Agree		
There is a need for this procedure where transport times to hospital exceed 30 minutes.	Agree		
There is a need for this procedure where transport times to hospital exceed 60 minutes.	Strongly Agree		
It would benefit patients if there are more providers of this procedure pre-hospital.	Agree		
There is a need for this procedure pre-hospital for prolonged entrapped patients when indicated.	Strongly Agree		
Patients will benefit greatly if this procedure is performed earlier.	Agree		
There is a need for this procedure pre-hospital where indicated in cardio-pulmonary resuscitation.	Strongly Agree		
There is a need for this procedure in aviation emergency medical care.	Strongly Agree		
Where clinically indicated, this procedure limits morbidity and mortality.	Agree		
Further studies are required to determine the need for this procedure pre-hospital.	Strongly Agree		

2. SAFETY OF PROCEDURE: *(Risk/Complications vs. Benefit/Improved Patient Outcomes)*	TREND	YOUR RATING	RE-EVALUATION
| 1 2 | 3 4 | 5 | 6 7 | 8 9 |			
Strongly Disagree *Disagree* *Neither Agree nor Disagree* *Agree* *Strongly Agree*			
The benefit of this procedure pre-hospital outweighs the risk.	Neither		
The risk of infection outweighs the benefit of this procedure pre-hospital.	Neither		
The risk of infection from this procedure pre-hospital can be suitably treated in-hospital.	Agree		
Complications of this procedure pre-hospital can be suitably treated in-hospital.	Agree		
Complications of this procedure pre-hospital can be limited by appropriate technique.	Agree		
Practitioners should be able to manage possible complications appropriately pre-hospital.	Strongly Agree		
This procedure has been seen performed successfully pre-hospital.	Neither		
Patients seen treated with this procedure pre-hospital have benefitted greatly.	Neither		
This procedure performed pre-hospital has shown minimal complications.	Neither		
This procedure should be limited to controlled environments.	Disagree		
This procedure has shown improved patient clinical outcome in-hospital.	Strongly Agree		
There is an increased risk using a Trochar device in performance of this procedure.	Strongly Agree		
With appropriate training, this procedure should be safe when indicated pre-hospital.	Strongly Agree		
There will be an increase in scene time if this procedure is performed pre-hospital.	Agree		
An increase in scene time pre-hospital will negatively affect patient outcome.	Strongly Agree		
Patients need to be transported rapidly to a hospital facility following this procedure.	Strongly Agree		
This procedure can be done safely pre-hospital if practitioners are adequately trained.	Strongly Agree		
This procedure can be done safely pre-hospital if practitioners are adequately equipped.	Strongly Agree		
This procedure pre-hospital has the risk of introducing a haemothorax.	Agree		
This procedure pre-hospital has the risk of introducing a pneumothorax.	Agree		
Draining a large haemothorax pre-hospital may lead to uncontrollable bleeding.	Strongly Agree		
This procedure pre-hospital would be purposeless where a patient requires a thoracotomy.	Disagree		
Where this procedure is clinically indicated it will potentially benefit peri-arrest patients.	Agree		
This procedure performed pre-hospital will allow practitioners to successfully manage haemothoraces.	Agree		
This procedure performed pre-hospital will allow practitioners to successfully manage pneumothoraces.	Strongly Agree		
Pre-hospital practitioners will be able to maintain the required skill to perform procedure.	Agree		

3. DIAGNOSIS OF MAJOR HAEMO-, PNEUMOTHORACES: *(Indications, Contraindications, Methods of Clinical Diagnosis)*	TREND	YOUR RATING	RE-EVALUATION
| 1 2 | 3 4 | 5 | 6 7 | 8 9 |			
Strongly Disagree *Disagree* *Neither Agree nor Disagree* *Agree* *Strongly Agree*			
Diagnosis of major haemothoraces should only be clinical.	Disagree		
Diagnosis of major pneumothoraces should only be clinical.	Disagree		
Practitioners should possess sound clinical judgement when diagnosing haemothoraces.	Strongly Agree		
Practitioners should possess sound clinical judgement when diagnosing pneumothoraces.	Strongly Agree		
Suitable pre-hospital clinical diagnosing methods should be utilized when diagnosing haemothoraces.	Strongly Agree		
Suitable pre-hospital clinical diagnosing methods should be utilized when diagnosing pneumothoraces.	Strongly Agree		
Suitable pre-hospital clinical diagnosing equipment should be utilized when diagnosing haemothoraces.	Strongly Agree		
Suitable pre-hospital clinical diagnosing equipment should be utilized when diagnosing pneumothoraces.	Strongly Agree		
A combination of clinical and special investigations should be utilized when diagnosing haemothoraces.	Strongly Agree		
A combination of clinical and special investigations should be utilized when diagnosing pneumothoraces.	Strongly Agree		
This procedure should only be done after X-ray diagnosis confirmation.	Srongly Disagree		
X-ray diagnosis and placement confirmation should be done after the procedure.	Strongly Agree		
This procedure can be performed if diagnosing haemothoraces is limited to clinical investigations.	Neither		
This procedure can be performed if diagnosing pneumothoraces is limited to clinical investigations.	Agree		
If a needle thoracenthesis is indicated, so is this procedure.	Strongly Agree		
This procedure should be limited to patients who are in immediate clinical danger.	Strongly Agree		
Large haemothoraces will not often be life threatening.	Disagree		
Large pneumothoraces will not often be life threatening.	Disagree		
A massive pneumothorax has a low risk of tensioning if the patient is not positively pressure ventilated.	Strongly Disagree		
A tension pneumothorax must first be needle decompressed before attempting this procedure.	Strongly Agree		
This procedure requires extensive patient monitoring.	Strongly Agree		
Ultrasound is the method of choice for pre-hospital diagnosing of haemothoraces.	Agree		
Ultrasound is the method of choice for pre-hospital diagnosing of pneumothoraces.	Strongly Agree		
Evidence based guidelines and norms should apply when diagnosing haemothoraces pre-hospital.	Strongly Agree		
Evidence based guidelines and norms should apply when diagnosing pneumothoraces pre-hospital.	Strongly Agree		

4. EFFECTIVENESS OF PROCEDURE: *(Treatment of Injury, Patient Outcome Measures)*	TREND	YOUR RATING	RE-EVALUATION
| 1 2 | 3 4 | 5 | 6 7 | 8 9 |			
Strongly Disagree *Disagree* *Neither Agree nor Disagree* *Agree* *Strongly Agree*			
This procedure is the gold standard for treating haemothoraces.	Agree		
This procedure is the gold standard for treating pneumothoraces.	Agree		
Where indicated pre-hospital, this procedure will improve patient outcome.	Agree		
This procedure performed pre-hospital will improve long-term patient outcome.	Strongly Agree		
This procedure is effective if performed correctly pre-hospital.	Agree		
Pre-hospital effectiveness of this procedure is difficult to measure.	Agree		
Pre-hospital outcomes of this procedure should be measured against hospital outcomes.	Agree		
There is a high morbidity from incorrect procedure placement pre-hospital.	Agree		
Pre-hospital procedure efficacy can be assessed clinically.	Agree		
This procedure is more effective than an informal needle decompression.	Strongly Agree		
Long term efficacy of this procedure pre-hospital need to be through a monitoring perspective (in terms of infection and discharge from hospital).	Strongly Agree		
Appropriate algorithms will guide practitioners to perform this procedure effectively pre-hospital.	Strongly Agree		
Strict protocols need to be in place to ensure that patients' ultimately benefit from this procedure pre-hospital.	Strongly Agree		
Consultation with suitable practitioners should be available prior to performing this procedure pre-hospital.	Strongly Agree		
Consultation with suitable practitioners should be mandatory prior to performing this procedure pre-hospital.	Strongly Agree		
5. SKILL LEVEL REQUIRED TO PERFORM PROCEDURE: *(Medical Doctors, Emergency Care Pracitioners (Degree qualified), Paramedics (CCA or N.Dip qualified)*	TREND	YOUR RATING	RE-EVALUATION
| 1 2 | 3 4 | 5 | 6 7 | 8 9 |			
Strongly Disagree *Disagree* *Neither Agree nor Disagree* *Agree* *Strongly Agree*			
Only medical doctors should be allowed to perform this procedure pre-hospital.	Disagree		
Medical doctors with ED or surgical experience are preferred to perform this procedure pre-hospital.	Strongly Agree		
Specially trained professional nurses should be allowed to perform this procedure pre-hospital.	Neither		
Emergency Care Practitioners (Degree qualified) with appropriate training should be allowed to perform this procedure pre-hospital.	Agree		
All advanced life support practitioners with appropriate training should be allowed to perform this procedure pre-hospital.	Agree		
All skill levelled practitioners can be trained to perform this procedure pre-hospital.	Strongly Disagree		
Mature and experienced practitioners are preferred to perform this procedure pre-hospital.	Agree		
A high skill levelled practitioner is required to perform this procedure pre-hospital.	Agree		
This procedure can be successfully performed by a single practitioner.	Disagree		
The performance of this procedure pre-hospital should form part of formal training.	Strongly Agree		
This procedure can be selectively utilized pre-hospital by appropriately trained practitioners.	Agree		

6. EQUIPMENT: *(Required and/or Available to Perform Procedure)*	**TREND**	**YOUR RATING**	**RE-EVALUATION**
| 1 2 | 3 4 | 5 | 6 7 | 8 9 |			
Strongly Disagree *Disagree* *Neither Agree nor Disagree* *Agree* *Strongly Agree*			
All equipment used during this procedure pre-hospital should be sterile packaged.	Strongly Agree		
Pre-packaged kits should be available to perform this procedure pre-hospital.	Strongly Agree		
All kits used during this procedure pre-hospital should be sealed.	Strongly Agree		
All kits used during this procedure pre-hospital should be standardised.	Strongly Agree		
Appropriate equipment to perform this procedure pre-hospital is not currently available.	Disagree		
Similar equipment utilized in-hospital to perform this procedure should be utilized pre-hospital.	Agree		
Similar equipment utilized on aeromedical services to perform this procedure should be utilized pre-hospital.	Strongly Agree		
Sufficient cleansing solutions need to be utilized to reduce the risk of infection.	Strongly Agree		
Appropriate monitoring equipment should be utilized to evaluate a patient's condition during performance of this procedure.	Strongly Agree		
Alternative drainage devices are available to suit the pre-hospital environment.	Strongly Agree		
Simplified procedure equipment can be utilized to suit the pre-hospital environment.	Agree		
Simplified drainage devices can be utilized to suit the pre-hospital environment.	Agree		
7. OTHER: *(Any other issues regarding the placement of pre-hospital intercostal chest drains in South Africa)*	**TREND**	**YOUR RATING**	**RE-EVALUATION**
| 1 2 | 3 4 | 5 | 6 7 | 8 9 |			
Strongly Disagree *Disagree* *Neither Agree nor Disagree* *Agree* *Strongly Agree*			
There is no need for this procedure pre-hospital in South Africa.	Strongly Disagree		
This procedure will lead to unnecessarily long pre-hospital scene time.	Agree		
There is a big risk of misdiagnosing haemothraces pre-hospital.	Agree		
There is a big risk of misdiagnosing pneumothraces pre-hospital.	Agree		
A tension pneumothorax can be successfully managed with a needle decompression pre-hospital.	Disagree		
This procedure can be a module as part of the emergency care practitioner training.	Agree		
Practitioners will have to maintain a high skill level to perform this procedure pre-hospital.	Strongly Agree		
Integration with hospital trauma units is required to maintain practitioner competency in the performance of this procedure pre-hospital.	Strongly Agree		
Regular training and skill maintenance of this procedure pre-hospital is required to maintain practitioner competency.	Strongly Agree		
Training of this procedure pre-hospital should be conducted under the guidance of a suitable medical practitioner.	Strongly Agree		
This procedure can be performed in transit.	Disagree		
Clinical governance and quality assurance need to be in place to manage the performance of this procedure pre-hospital.	Strongly Agree		
A good record of information should be maintained regarding the performance of this procedure pre-hospital.	Strongly Agree		
Uncontrolled conditions pre-hospital create hazardous complications to the performer of this procedure.	Agree		
Clinical trails need to be carried out to establish the efficacy of this procedure pre-hospital.	Agree		

(APPENDIX 6) – Focus Group Discussion Points

FOCUS GROUP DISCUSSION POINTS

(27/02/2013 – IPM BUILDING, EMERGENCY PHYSICIAN REGISTRARS)

NEED FOR PROCEDURE:

- Unclear what particular type of need there are, but group does agree that there is some sort of anecdotal need as prevalent in the chest trauma increase in SA.
- Concerned of Urban vs. Rural need, yet acknowledges national protocol framework.
- Short transport times to hospital may negate the need for ICD placement pre-hospital.
- Does support possible CPR insertion, if indications are met.
- Need to have the procedure available pre-hospital if the need arises.
- Further specific study is needed to determine exact need.
- Pre-hospital need may be greater for unstable life threatening cases – needs analysis.

SAFETY OF PROCEDURE:

- Group unanimously agree that the procedure can be done safely pre-hospital, yet sterility is a concern.
- Risk vs. Benefit will have to be determined on individual cases and circumstances.
- Treatment of complications of ICD placement a concern pre-hospital, yet ALS should be able to manage such complications till arrival at hospital.
- Procedure should be safe if effective training, equipment and SOP's are in place.

DIAGNOSIS OF MAJOR HAEMO-, PNEUMOTHORACES:

- ALS should be able to diagnose such conditions accurately.
- Clinical diagnosis alone can be done successfully by ALS.
- Diagnosis of Minor Haemo-, Pneumothoraces may not require ICD placement pre-hospital.
- X-Ray and portable Ultrasound need not be necessary in life threatening cases, yet has to be confirmed in-hospital.
- Clear indications should be set up and met prior insertion pre-hospital.

EFFECTIVENESS OF PROCEDURE:

- Procedure is much more effective than needle decompression.
- Group agrees that this procedure is the best way of managing haemo-, pneumothoraces.
- Different techniques like finger sweep thoracenthesis may be as effective, if not more viable pre-hospital.

SKILL LEVEL REQUIRED TO PERFORM PROCEDURE:

- ALS Paramedics are of adequately skill level to be taught the procedure and to perform it.
- Doctors
- Practitioners appropriately trained in all aspects of the procedure.
- Skill requires monitoring and evaluation.
- Skill is deemed as a 'simple' surgical procedure.

EQUIPMENT:

- Standard in-hospital equipment should be made available.
- Alternative devices like Heimlich valves and bags may be appropriate.
- Trochar devices should be avoided.
- Equipment should be provided to meet the need of the procedure.

OTHER:

- Quality assurance, clinical governance, review and skill monitoring should be in place.
- Record keeping and mortality evaluations should be maintained.

(APPENDIX 7) – Faculty of Health Sciences Human Research Ethics Committee Letter

UNIVERSITY OF CAPE TOWN

Health Sciences Faculty
Human Research Ethics Committee
Room E52-24 Groote Schuur Hospital Old Main Building
Observatory 7925
Telephone (021) 406 6338 • Facsimile (021) 406 6411
e-mail: shurette.thomas@uct.ac.za

27 June 2012

HREC REF: 317/2012

Mr E Dippenaar
c/o Prof L Wallis
Emergency Medicine
Department of Surgery

Dear Mr Dippenaar

PROJECT TITLE: IDENTIFYING THE ROLE OF PRE-HOSPITAL INTERCOSTAL CHEST DRAINS IN SOUTH AFRICA

Thank you for submitting your study to the Faculty of Health Sciences Human Research Ethics Committee for review.

It is a pleasure to inform you that the HREC has **formally approved** the above-mentioned study.

Approval is granted for one year till the 15th July 2013

Please submit a progress form, using the standardised Annual Report Form if the study continues beyond the approval period. Please submit a Standard Closure form if the study is completed within the approval period.
(Forms can be found on our website: www.health.uct.ac.za/research/humanethics/forms)

Please note that the ongoing ethical conduct of the study remains the responsibility of the principal investigator.

Please quote the HREC. REF in all your correspondence.

Yours sincerely

pp
PROFESSOR M BLOCKMAN
CHAIRPERSON, HSF HUMAN ETHICS
Federal Wide Assurance Number: FWA00001617.

Institutional Review Board (IRB) number: IRB0001938
This serves to confirm that the University of Cape Town Human Research Ethics Committee complies to the Ethics Standards for Clinical Research with a new drug in patients, based on the Medical Research Council (MRC-SA), Food and Drug Administration (FDA-USA), International Convention on Harmonisation Good Clinical Practice (ICH GCP) and Declaration of Helsinki guidelines.
The Human Research Ethics Committee granting this approval is in compliance with the ICH Harmonised Tripartite Guidelines E6: Note for Guidance on Good Clinical Practice (CPMP/ICH/135/95) and FDA Code Federal Regulation Part 50, 56 and 312.

(APPENDIX 8) –

Participant Consent Form

PARTICIPANT CONSENT FORM

TITLE OF THE RESEARCH PROJECT:

Identifying the role of pre-hospital intercostal chest drains in South Africa

UNIVERSITY:	University of Cape Town (UCT)
FACULTY:	Health Sciences
DIVISION:	Emergency Medicine
STUDENT:	Mr Enrico Dippenaar (DPPENR001)
EMAIL ADDRESS:	edippenaar@mweb.co.za
CONTACT NUMBER:	083 585 1888
SUPERVISOR:	Professor Lee Wallis
EMAIL ADDRESS:	leewallis@bvr.co.za
CONTACT NUMBER:	021 – 948 9908
STUDY APPROVAL REFERENCE:	HREC REF: 317/2012

Declaration by participant

By signing below, I *(name)* ……..…… agree to take part in a research study entitled: Identifying the role of pre-hospital intercostal chest drains in South Africa.

I declare that:

- I have read or had read to me the participant information and consent form and it is written in a language with which I am fluent and comfortable.
- I have had a chance to ask questions and all my questions have been adequately answered.

- I understand that taking part in this study is **voluntary** and I have not been pressurised to take part.
- I may choose to leave the study at any time and will not be penalised or prejudiced in any way.
- I may be asked to leave the study before it has finished, if the study researcher feels it is in my best interests, or if I do not follow the study plan, as agreed to.

Signed at (*place*) .....…..…… on (*date*)……...…….. 2012.

.....

Signature of participant

Declaration by investigator

I *(name)* ……..…… declare that:

- I made explained the study information to ……
- I encouraged him/her to ask questions and took adequate time to answer them.
- I am satisfied that he/she adequately understands all aspects of the research, as discussed above.
- I did/did not use an interpreter.

Signed at (*place*) .....…..…….. on (*date*) ……...…… 2012.

.....

Signature of investigator

(APPENDIX 9) –
Research Information Leaflet

RESEARCH INFORMATION LEAFLET

TITLE OF THE RESEARCH PROJECT:

Identifying the role of pre-hospital intercostal chest drains in South Africa

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UNIVERSITY:	University of Cape Town (UCT)
FACULTY:	Health Sciences
DIVISION:	Emergency Medicine
STUDENT:	Mr Enrico Dippenaar (DPPENR001)
EMAIL ADDRESS:	edippenaar@mweb.co.za
CONTACT NUMBER:	083 585 1888
SUPERVISOR:	Professor Lee Wallis
EMAIL ADDRESS:	leewallis@bvr.co.za
CONTACT NUMBER:	021 – 948 9908
STUDY APPROVAL REFERENCE:	HREC REF: 317/2012

Dear prospective participant:

You are being invited to take part in a research project. Please take some time to read the information presented here, which will explain the details of this project. Please ask the study investigator any questions about any part of this project that you do not fully understand. It is very important that you are fully satisfied and that you clearly understand what this research entails and how you could be involved. Also, your participation is **entirely voluntary** and you are free to decline to participate. If you say no, this will not affect you negatively in any way whatsoever. You are also free to withdraw from the study at any point, even if you do agree to take part.

This study has been approved by the **Health Research Ethics Committee at the University of Cape Town** and will be conducted according to the ethical guidelines and principles of the international Declaration of Helsinki, South African Guidelines for Good Clinical Practise and the Medical Research Council (MRC) Ethical Guidelines for Research.

What is this research study all about?

- The aim of this study is to highlight issues regarding the placement of intercostal chest drains in the pre-hospital environment in South Africa.
- The objectives of this study is to identify key issues of relevance to the question of whether intercostal chest drains have a role in the pre-hospital environment in South Africa, and the current opinion of this role amongst South African emergency care experts. Issues expanded below seven specific headings and their subheadings will be reflected in recommendations, to provide hypothesis and idea generation for potential future research and policy development.
- A National three-round modified Delphi study will be conducted, followed by regional focus group interviews within the Western Cape.
- Emergency care specialist will be divided into two groups: emergency centre specialists (emergency medicine specialists and trauma surgeons) – group 1, and emergency medical services (emergency care practitioners and paramedics) – group 2.

Why have you been invited to participate?

- You are recognised by this study as an expert in the field of emergency medical care in South Africa.

What will your responsibilities be?

- You will be required to respond to communication sent to you by the investigator, completing and returning the relevant documents within the set timeframe.
- If selected to take part in the focus group interviews, you will be required to attend such interviews, with due consideration to your needs.

Will you benefit from taking part in this research?

- Your contribution to this study will provide expert input on key issues relating to the study.
- Future understanding and development of emergency medicine in South Africa may be affected by your participation.

Are there any risks involved in your taking part in this research?

- There should be no personal risk to you through your participation.
- Your individual authority and expert opinion will be respected at the highest level.

If you do not agree to take part, what alternatives do you have?

- Updated study information will be sent to you, unless otherwise requested.
- You may reconsider participation at any time during the study, and will be allowed to provide input up to the final data collection date; this will also be reflected on the statistical analysis of the study.

Who will have access to your information and participation?

- Information collected will be treated as confidential and protected on a personal password protected computer.
- If the information is used in a publication, your identity will remain anonymous.

Will you be paid to take part in this study and are there any costs involved?

- No you will not be paid to take part in the study. There should be no costs involved for you, if you do take part.
- The focus group interviews will be held in the Western Cape, and be facilitated in a convenient location to you, as far as is practically possible.

Is there anything else that you should know or do?

- You can contact the principle investigator if you have any further queries or encounter any problems.
- You can contact the Health Research Ethics Committee at 021-938 9207 if you have any concerns or complaints that have not been adequately addressed by the study investigator.
- You will receive a copy of the consent form for your own records.